FOIA Number: 2018-0758-F

FOIA MARKER

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Collection/Record Group: Clinton Presidential Records

Subgroup/Office of Origin: National AIDS Policy Office

Series/Staff Member: Todd Summers

Subseries:

OA/ID Number: 21089

FolderID:

Folder Title:
Issues - Medicaid Expansion [2]

Stack:	Row:	Section:	Shelf:	Position:
S	66	6	3	1

Talking Points on Post Article

• The Administration understands the importance of trying to find new and innovative ways to ensure that all people with HIV benefit from the promise of new and effective therapies. It is for this reason the Vice President directed the Department of Health and Human Services to explore the feasibility of a Medicaid expansion.

• The announcement by HHS that an HIV Medicaid expansion is not feasible **at the present time** in no way lessens the Administration's resolve to continue to seek workable means of extending life prolonging therapies to those in need.

• This is a complex matter and we need a strategy that pushes forward on multiple fronts. In the short run, we need to work with private insurers, Medicaid programs, drugs companies, and federal, state and local budgets to help find the additional resources that are needed.

-- Private insurers and Medicaid programs that do no cover these life saving therapies should;

-- Drug companies that have not reduced the price of these life saving therapies given the extent of our federal investment should; and

-- States that have not become partners in making these life saving therapies more widely available should.

-- The Administration will explore ways to ensure that future federal investments help to leverage these importance partnerships.

• In the long run, we need to continue to look at the growing number of uninsured Americans and figure out how best to secure their access to essential health services. And this effort must include HIV+ individuals who are uninsured and not yet eligible for Medicaid.

• The President has long been committed to health care for all Americans, and is pleased with the incremental progress that has been made on a bipartisan basis in recent years. Insurance reform and increased access to health insurance for children are important first steps. But the ultimate goal of high quality health insurance for all Americans remains.

AIDS Medicaid Demonstration - Talking Points (Zonana, HHS: 690-6343)

11/26

Background: In April, the Vice President directed the Health Care Financing Administration and the Office of National AIDS Policy to determine the feasibility of establishing a demonstration to permit earlier Medicaid coverage for HIV positive individuals, and to report back within 30 days.

TPs:

- · Clearly the analysis was complicated and took longer than we expected. The question is far more complex than many believed it to be. Perhaps our past successes in AIDS - most notably, the rapid development and approval of life-prolonging treatments -- made us too optimistic.

- · After rigorous analysis of the many complex policy issues, including costs, HCFA and ONAP are not able to determine a revenue neutral method to establish a demonstration project in this area.

- · The Administration remains strongly committed to making sure that as many HIV-positive individuals receive appropriate drug therapy as possible.

The President recently signed a fiscal 1998 appropriations bill that provides $285.5 million for the AIDS Drug Assistance Program, a 71% increase from FY1997.

Medicaid is the largest single payer for AIDS services and AIDS drug therapies in the country. In 1997, federal Medicaid expenditures for people living with HIV/AIDS totaled $1.8 billion, including nearly $500 million for AIDS drugs.

- · The Administration will continue to work with Congress, patient advocates, States, pharmaceutical manufacturers, and others to find innovative ways to expand coverage for low-income individuals living with HIV.

TALKING POINTS ON
MEDICAID EXPANSION TO PEOPLE WITH HIV

Background

In April, the Vice President directed the Health Care Financing Administration (HCFA) of HHS to determine the feasibility of establishing a demonstration program to expand Medicaid coverage to people who were HIV -- and do not currently qualify for Medicaid benefits. This was in response to a release by HHS of a standard of care for HIV and AIDS that recommended early treatment. The Vice President asked HHS to report back within 30 days.

Under current regulations, Medicaid coverage is not availalable to many individuals with HIV until they progress to AIDS; the new treatments offer the promise of forestalling the progression to AIDS, creating a "catch 22" whereby individuals can't get the drugs that would keep them from progressing to AIDS until they get AIDS.

Talking Points

- The Clinton Administration remains strongly comitted to insuring that people living with HIV and AIDS have access to the medical treatments they need.

- The experts at HCFA are finding it difficult to make this expansion cost neutral, which is the test that we must meet to change benefits without Congressional action

- The Administration is still in active dialogue with community members, Congress, and public policy experts to refine the financial analysis -- we have not shut the door on making this work

- The anaylsis turned out to be far more complicated than many believed it to be, so it is taking much more time than we thought it would. However, the Administration is still actively working on a solution to this problem.

Administration has a strong track record of addressing the needs of people living with HIV and AIDS

- the President recently signed a fiscal year 1998 appropriation bill that provides $286 million for the State AIDS Drug Assistance Program, a 71% increase from fiscal year 1997.

•the President worked vigorously to save the Medicaid program, which is the largest single payor for AIDS services and treatment in the country -- in 1997, federal Medicaid expenditures for people living with HIV/AIDS totaled $1.8 billion, including nearly $500 million for AIDS drugs.

•the President has long been committed to health care for all Americans, and is pleased with the incremental progress that has been made on a bipartisan basis in recent years. Insurance reform and increased access to health insurance for children are important first steps. But the ultimate goal of high quality health insurance for all Americans remains.

Record Type: Record

To:

cc:
Subject: Talking Points for AIDS Medicaid Expansion

TALKING POINTS ON
MEDICAID EXPANSION TO PEOPLE WITH HIV

Background
In April, the Vice President directed the Health Care Financing Administration of HHS to determine the feasibility of establishing a demonstration program to expand Medicaid coverage to people who were HIV+ and did not currently qualify for Medicaid benefits. This was in response to a release by HHS of a standard of care for HIV and AIDS that recommended early treatment. The Vice President asked HHS to report back within 30 days.

Under current regulations, Medicaid coverage is not availalable to many individuals with HIV until they progress to AIDS; the new treatments offer the promise of forestalling the progression to AIDS, creating a "catch 22" whereby individuals can't get the drugs that would keep them from progressing to AIDS until they get AIDS.

Talking Points
- The Clinton Administration remains strongly comitted to insuring that people living with HIV and AIDS have access to the medical treatments they need.
- the Vice President asked for the feasibility anaylses to explore a limited expansion of Medicaid coverage to address the needs of people infected with HIV who cannot afford the costly new treatments
- the new treatments have radically changed the epidemic, making it very difficult to accurately assess the cost impact of expanding Medicaid coverage
- at this time, we are finding it ~~more~~ difficult to make this expansion cost neutral, which is the test that we must meet to change benefits without Congressional ~~approval~~ action
- we are still in dialogue with community members, Congress, and public policy experts to refine the financial analysis -- we have not shut the door on making this work
- because of the complexity of the analysis, it is taking much more time than we thought it would, but we are still actively working on a solution

Administration has a strong track record of addressing the needs of people living with HIV and AIDS
- the President recently signed a fiscal year 1998 appropriation bill that provides $286 million for the State AIDS Drug Assistance Program, a 71% increase from fiscal year 1997.
- the President worked vigorously to save the Medicaid program, which is the largest single payor for AIDS services and treatment in the country -- in 1997, federal Medicaid expenditures for people living with HIV/AIDS totaled $1.8 billion, including nearly $500 million for AIDS drugs.

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Talking Points
- The Clinton Administration remains strongly comitted to insuring that people living with HIV and AIDS have access to the medical treatments they need.
- The experts at HCFA are finding it difficult to make this expansion cost neutral, which is the test that we must meet to change benefits without Congressional action
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- the President worked vigorously to save the Medicaid program, which is the largest single payor for AIDS services and treatment in the country -- in 1997, federal Medicaid expenditures for people living with HIV/AIDS totaled $1.8 billion, including nearly $500 million for AIDS drugs.

AIDS Medicaid Demonstration - Talking Points (Zonana, HHS: 690-6343)

11/26

Background: In April, the Vice President directed the Health Care Financing Administration [redacted] to determine the feasibility of establishing a demonstration to permit earlier Medicaid coverage for HIV positive individuals, and to report back within 30 days.

TPs:

- · Clearly the analysis was complicated and took longer than we expected. The question is far more complex than many believed it to be. Perhaps our past successes in AIDS - most notably, the rapid development and approval of life-prolonging treatments – made us too optimistic.

- · After rigorous analysis of the many complex policy issues, including costs, HCFA has not yet been able to determine a revenue neutral method to establish a demonstration project in this area. [redacted] However, we

- · The Administration remains strongly committed to making sure that as many HIV-positive individuals receive appropriate drug therapy as possible who need these drugs have access to them.

The President recently signed a fiscal 1998 appropriations bill that provides $285.5 million for the AIDS Drug Assistance Program, a 71% increase from FY1997.

Medicaid is the largest single payer for AIDS services and AIDS drug therapies in the country. In 1997, federal Medicaid expenditures for people living with HIV/AIDS totaled $1.8 billion, including nearly $500 million for AIDS drugs.

- · The Administration will continue to work with Congress, patient advocates, States, pharmaceutical manufacturers, and others to find innovative ways to expand coverage for low-income individuals living with HIV.

[redacted]

Close the loop on those who have don't have access to health coverage

States
Drug Companies
Insurance Companies
Feds for pennies

OMNI HOTELS®

Medicaid Expansion

Recent mtg with Nancy Ann Minn DeParle and other HCFA officials
- including actuaries

Went through their analysis step-by-step

- discussed their assumptions

Looked at:

- expanding Medicaid coverage to all people with HIV or AIDS who don't otherwise qualify
- looked at different breaks at federal poverty level

Not cost neutral

Need to continue dialogue

- Commitment by Nancy Ann to continue

Community made clear this was about access to entitlement funding

Our office will work to address unmet needs through existing discretionary prog's.

State waivers, data collection, reduced benefits

Estimated Net Costs of Expanding Medicaid to Cover HIV-Positive Individuals

Eligibility Level (% of FPL)	Federal+State Cost ($billion) Year 1	Year 2	Year 3	Year 4	Year 5	Total	No. Participants Year 1 (000)
100%	$ 0.4	$ 0.3	$ 0.3	$ 0.3	$ 0.3	$ 1.5	46,000
200%	0.8	0.7	0.6	0.6	0.6	3.2	80,000
250%	0.9	0.8	0.8	0.7	0.7	3.9	90,000
300%	1.1	1.0	0.9	0.8	0.8	4.5	100,000

Key Assumptions:

No. of HIV+ without AIDS	500 thousand
Know status	50%
Annual CDT drug cost	$ 12,000
Other Medicaid cost	$ 4,000
Medicaid cost for persons with AIDS	$ 30,000
No. years CDT treatment	5
Proportion of insured who have CDT coverage	80%
Proportion of insured switching to Medicaid	30%
Proportion for whom CDT effective - year 1	80%
- year 2+	97.5%
Annual AIDS progression rate	15%
Medicaid participation rate for PWAs (curr. law)	75%
Income and coverage distributions	estimated from Census/CDC data

2 insured - 30% uninsured

? COBRA payments, Medigap, etc. ? Not in here

?

OACT
HCFA
10/27/97

Elasticities of Key Assumptions

Percent Increase in Cost for Each 1% Increase in Input Variable

	1st Year	5-Year
CDT Cost	0.8	1.0
Initial Medicaid Other Cost	0.3	0.4
Medicaid PWA Cost	-0.1	-0.4
No. Yrs CDT treatment	0.0	-16.2 **
% of insured w/ CDT coverage	-0.3	-0.1
% of ins w/ CDT switching to Medicaid	0.2	0.3
Portion for whom CDT effective - year 1	0.2	0.5
- year 2+	0.0	0.9
Annual AIDS progression rate	-0.1	-0.3
Annual growth in new (aware) infections	0.1	0.2

**Represents impact of reducing length of CDT treatment from 5 to 4 years.

THE WHITE HOUSE

WASHINGTON

Christine Lutinski

= Jeff Levi

= Miguelina

= Jeff Conley

= Robert Greenwald

- Susan Dooha - GMHC -

- Public Hosp. Julie Rocchio
624-7250

Lee Partridge
- APW
682-0100

Joe Kelly - NASTAD

Ron Nevin
- 797-0007

AIDS Action council

Medicaid Expansion Meeting
March 11, 1997

Administration Participants

HCFA
Bruce Vladeck
Administrator

Sally Richardson
Acting Deputy Administrator

Kathy King
Special Assistant to the Administrator

Kathy Buto
Associate Administrator for Policy

Jerry Zellinger
Technical Director Office of Medical Services
Medicaid Bureau

Debbie Chang
Director, Office of Legislative and
Intergovernmental Affairs

Bruce Fried
Director, Office of Managed Care

Bill Clark
Program Analyst - Office of Research and Demonstration

OMB

Nancy-Ann Min
Associate Director for Health and Personnel

Greg White
Staff Specialist (categorical AIDS funding)

Meg Murray
Staff Specialist (Medicaid)

1875
Connecticut Ave NW
Suite 700
Washington DC
20009
Fax 202 986 1345
Tel 202 986 1300

FAX MEMORANDUM

AIDS Action

TO: Daniel Montoya

FAX #: 202-632-1096

FROM: Amy Andersen, ext. 3028

DATE: October 21, 1997

RE: Medicaid expansion meeting

PAGES (including cover page): 2

* *

Attached is a list of Clinton Administration officials with whom we met about the proposal to expand Medicaid eligibility to low-income HIV-positive individuals. Please feel free to contact me if you have any further questions.

1875
Connecticut Ave NW
Suite 700
Washington DC
20009
Fax 202 986 1345
Tel 202 986 1300
Email
hn3384@handsnet.org

If you experience difficulty in receiving this fax, please call 202/986-1300.

Medicaid Expansion Meeting 10/3/97

5,000 people @ 10 years / lifetime = +

NPV { $100mm/yr
$ 60mm/yr drugs

- including look at savings/costs outside Medicaid
- NIH/CDC → ethical issues of limited access
- HCFA meet w/ community + present actuarial data

Alternatives

COBRA gap / Medigap
ADAP

ADAP → let Congress take the lead??

Demo →

Todd A. Summers
08/12/97 06:17:14 PM

Record Type: Record

To: Christopher C. Jennings/OPD/EOP

cc:
Subject: Pillars

Here are a few items for the pillars document (vaccine, Medicaid, needle exchange). I am waiting for a fax from Eric on others - he's out of town at an all-day meeting.

Also, FYI, there may be a large demonstration on Sept. 16th in front of HHS on needle exchange.

Todd

Building Blocks of Pillar
AIDS Vaccine Initiative

Description
Develop an AIDS vaccine (or vaccines) to prevent the transmission of HIV. The initiative will be located at the National Institutes of Health, bringing together researchers who have come to better understand how HIV works to destroy the immune system with the vaccinologists who can use that information to craft vaccines to prevent infection. Partnership with the pharmaceutical industry and the other developed nations is also a key component of the initiative.

Timeline
Within 10 years.

Benefits
Stop the spread of HIV as a critical component of the nation's strategy to end the AIDS epidemic. This will be important not only in the United States but particularly in developing countries, where access to promising new treatments for AIDS are not likely to be accessible because of high cost and lack of supportive health care and supportive services.

Costs/Feasibility
Much of the initiative will involve increasing coordination and communication between researchers, so costs specifically related to new research will be lower. Capital costs for the physical plant are available through the current NIH capital budget. An accurate estimate of costs will follow the development of an implementation strategy for the initiative, which is pending.

Political Ramifications
Has strong support from community groups and key Congressional offices, as well as international health, AIDS, and vaccine groups. Support from the "G7+1" was incorporated into a joint communique issued at the Denver summit. Concerns include: (1) need to adequately fund; (2) cannot pull research positions or dollars from other areas of AIDS research; and (3) must work toward vaccines which are easily administered and economical.

Building Blocks of Pillar
Expand access to HIV treatments through expaned access to Medicaid benefits.

Description
Poor people infected with HIV are unable to access medical care and new treatments that might forestall illness because Medicaid benefits are tied to a finding of disability. Treatment guidelines recently released by HHS recommend treatment at earlier stages of infection before the onset of AIDS or disabling opportunistic infections. In response to this need for earlier treatment access, the Vice President recently announced a study by HCFA to determine how some Medicaid benefits could be available prior to disability.

Timeline
The VP requested the study within 30 days; HCFA has been unable to complete its analysis in that time frame, partly because it appears that any kind of expanded Medicaid access initiative would (using their prescribed methods for cost analysis) increase Medicaid expenditures substantially.

Benefits
Expanding access to Medicaid benefits at earlier stages of HIV infections would allow individuals to remain healthier longer, and therefore to remain productive longer. In addition, health care costs from HIV-related illnesses would be reduced. This initiative would also help reduce the pressure on the AIDS Drug Assistance Program (ADAP), which is part of the Ryan White CARE Act.

Costs/Feasibility
A fiscal impact anaylsis is currently underway. The results of that analysis dictate next steps. One possible outcome would be a legislated expansion, which may prove difficult under the current budgetary pressures on the Medicaid program.

Political Ramifications
Community groups and the President's Advisory Council on HIV/AIDS are watching this issue closely, both in anticipation of having another tool to provide potentially life-saving care to the indigent and as a measure of the VP's effectiveness on an AIDS initiative.

Building Blocks of Pillar
Lift the restriction on use of federal funds for needle exchange

Description
The Secretary of HHS (in the absence of a Surgeon General) has authority to lift the restriction on the use of federal funds for needle exchange programs if she determines that such programs slow the spread of HIV infection and do not increase drug use among participants.

Timeline
There is increasing momentum toward action by the Secretary to exercise her authority to lift the restriction, although no formal decision for such action has been made.

Benefits
HIV infections among injection drug users, their sexual partners, and their children are at a very high level and are increasing. Needle exchange programs have been shown to be effective in reducing the rates of needle sharing and HIV infection among participants. More limited data seems to indicate that needle exhange programs do not increase drug activity by participants. Federal support would provide funding and moral support for local prevention groups and public health officials seeking to implement programs at the community level.

Costs/Feasibility
Needle exchange programs themselves are relatively inexpensive; however, drug treatment slots, which are critical to serving participants who decide to seek treatment, are expensive and in short supply. Community and political acceptance of needle exchange programs are impacted by the availability of linked treatment slots.

Political Ramifications
Needle exchange remains a controversial method of reducing HIV transmission largely out of concern that it sends a mixed message on acceptance of drug use. Republican appropriators were close to rescinding the Secretary's authority to lift the restriction, but did not do so. Many national organizations, including the U.S. Conference of Mayors, the American Medical Association, and the American Bar Association, have come out in support of needle exchange.

SAMPLE

EDUCATION PILLAR					
BUILDING BLOCKS OF PILLAR	**DESCRIPTION**	**TIMELINE**	**BENEFITS** (e.g. Who does this help? How does it help them?)	**COSTS/FEASIBILITY** (e.g. What does it take to achieve? Who pays ($ or capital)? What is the likelihood it will occur?)	**POLITICAL RAMIFICATIONS** (e.g. How does it affect the party?)
Educational Standards	Ensure that X of states sign on to standards for 4th and 8th grades thereby establishing a goal for students to reach. Ensure that schools and their teachers adequately prepare our children.	X months / years	Results in better educated students in public schools (as long as "failure" group does not develop). Results in measurement of school performance. Mainly helps students in X situation. There are Y students in that situation.	May entail high costs to organize efforts in each state where there are differing power centers / dynamics. Will require work to ensure that it is not used as a tool against minorities.	Has strong bi-partisan element. Sometimes results in alienation of minority community and may cause dissension within that area of the party.
Guarantee Two Years of Higher Education (Chaka Fattah Plan: 21st Century Scholars Act)	Guarantee Pell Grants to sixth-grade students from low income families.	X months / years	Increases college participation rates for this group, and broadly instills expectation of college attendance among lower-income students. 700,000 students available for benefit in first class. Promotes high school completion, job readiness and lower incidence of delinquent behavior.	$2.5 billion for first group of sixth-grade students. May create a new entitlement and will cost shift in budget priorities from one program to this one. May guarantee help to many non-needy students. Does not provide additional support like mentoring, tutoring and other support services that are critical for success.	Has bi-partisan support.
Additional building blocks to be added here.					

***Note that this example has both an old initiative that we are still developing and a new idea. Please include both in your input.**
***This template will be provided to you for incorporation of your own input.**

TEMPLATE

PILLAR					
BUILDING BLOCKS OF PILLAR	**DESCRIPTION**	**TIMELINE**	**BENEFITS** (e.g. Who does this help? How does it help them?)	**COSTS/FEASIBILITY** (e.g. What does it take to achieve? Who pays ($ or capital)? What is the likelihood it will occur?)	**POLITICAL RAMIFICATIONS** (e.g. How does it affect the party?)

1997 STATE OF THE UNION -- POLICIES ANNOUNCED
Tuesday, February 4, 1997

Unfinished business:

Balanced budget:

- Balance budget by 2002;

Campaign finance reform:

- Pass McCain-Feingold by 7/4;

Welfare reform:

- Finish reforming welfare -- move 2 million people from welfare to work by 2000.

Education:

Standards:

- Every state should adopt high national standards, and by 1999, every state should test every 4th grader in reading and every 8th grader in math;
- Teacher standards -- enable 100,000 more teachers to seek national certification as master teachers;

Literacy:

- America Reads -- at least 100,000 college students to volunteer as reading tutors;

Early learning:

- HRC conference on Early Learning and the Brain (spring);
- VP family conference on parents' involvement in learning (June);

Public school choice:

- Create 3,000 charter schools by the next century;

School construction:

- Pass $5 billion to help communities finance $20 billion in school construction over the next four years;

College opportunity:

- HOPE Scholarships;
- $10,000 tax deduction;
- Expanded IRA's;
- Largest increase in Pell Grants in 20 years;

Training:

- Pass G.I. Bill for America's Workers;

Education technology:

- Finish connecting every classroom and library to the Internet by the year 2000.

Science and technology:

Hospitals:

- Connect every hospital to Internet;
- Challenge private sector to connect every children's hospital to Internet;

Internet:

- Build the second generation of the Internet;

Medical research:

- Reinforce commitment to medical science (AIDS vaccine).

Stronger families:

Helping parents succeed at home and at work:

- Expand Family and Medical Leave;
- Pass flextime;

Health care:

- Extend health coverage to up to 5 million uninsured children;
- Reform Medicare; expand Medicare to cover respite care for Alzheimer's, annual mammograms;
- Guarantee woman can stay in hospital 48 hours after mastectomy;

Responsibility:

- Make it a felony for parent to cross state line to flee from child support;

Protecting children:

- Stand firm in determination to ban advertising/marketing of cigarettes aimed at kids.

Stronger communities:

Crime/drugs:

- Finish hiring 100,000 police;
- Pass Victims Rights Amendment;
- Pass Juvenile Justice bill;
- Largest anti-drug effort ever;

Urban agenda:

- Empower urban communities through investment and loans (double number of empowerment zones, restore contaminated urban land and buildings, expand community development banks);
- Use empowerment approach to renew DC;

Environment:

- Clean up 500 more toxic waste sites;
- Make polluters pay;
- Designate 10 American Heritage Rivers this year;
- Ban worst toxic chemicals and reduce greenhouse gases;

Service:

- Mobilize millions of Americans to national service;

Culture:

- America 2000 celebration of culture and the arts.

<u>World leadership</u>:

Undivided democratic Europe:

- Expand NATO by 1999, strengthen NATO's Partnership for Peace;

Asian Pacific community:

- Together with South Korea, advance peace talks with North Korea;
- Call on Congress to fund our share of agreement under which North Korea must freeze and dismantle nuclear weapons program;
- Pursue deeper dialogue with China (invited China's President to come here);

Global economy/trade:

- Expand exports, especially to Asia and Latin America (need authority to conclude new trade agreements);
- Will visit Latin America in the spring;

New security threats:

- Ratify Chemical Weapons Convention;

Military strength/tools:

- Increase funding for weapons modernization by year 2000, take care of men and women in uniform;
- Pay our debts and dues to international financial institutions like the World Bank, and to a reforming United Nations.

<u>One America</u>:

- ~~No specifics.~~ Race Initiative

THE WHITE HOUSE

WASHINGTON

August 11, 1997

MEMORANDUM FOR STRATEGY TEAM

FROM ERSKINE BOWLES AND SYLVIA MATHEWS

SUBJECT: Follow-up to Friday's Strategic Meeting

As a follow-up to last Friday's meeting, this memo details the assignments and their deadlines. A template is attached for you to use as you develop the assigned pillars. On Wednesday, a memo with your assigned pillar(s) will be due to Andrew Mayock by 5 p.m. On Thursday and Friday, Erskine will hold meetings to discuss the paper that has been produced and next week will be spent refining that paper. During the week of August 25th, Erskine and Sylvia will use the pillars as the foundation of a memo that we will send to the President on August 29th. When the President returns, we will meet with him to discuss the different choices among pillars and in some cases, within a single pillar.

PILLARS

1. Education - Reed, Sperling
2. Renewing our Cities (including sustainable development), Welfare, Underclass - Sperling, Reed, Klain
3. Environmental Protection - McGinty, Sperling, Gibbons
4. Crime/Drugs/Prisons (including perhaps, the future of young men) - Reed
5. Renewal of Family (issues like child care, balance of time, divorce, adoption, the media, family medical leave) - Verveer, Echaveste, Reed
6. Children - Sperling, Reed, Verveer, Echaveste
7. Racial Reconciliation (including civil rights enforcement, immigration, the judicial system) - Echaveste
8. International Economic Leadership - Tarullo, Summers, Sperling
9. Savings/Entitlement Reform - Sperling, Summers
10. American Leadership Abroad (including peace, defense structure, democracy) - Berger, Steinberg
11. Science/Technology (including reinvigorating the R/D budget, medical sciences, medical ethics) - Gibbons, Podesta, Gips, Sperling
12. Rego/Effectiveness of Government (like eliminating errors in Medicare or EITC) - Stone
13. Gifts to the Future (rebuilding our schools, the Millennium, museums, culture) - Verveer
14. Health Care/Improving Health Status (vaccination efforts, smoking reduction, adding years to the life span, decreasing suffering of elderly and sick, medical science improvement, more insured) - Jennings, Reed

Note: OMB and CEA will be a part of many of these issues.

There were a number of other ideas that came out of our brainstorming session. However, as the group tried to create a manageable number to produce detailed paper on, some items came off the primary list. The topics not included:

- Making Markets Work (negative ramifications of the modern economy, growing power of the corporation, new transactions, improving the framework of competition)
- Culture
- President as Teacher
- New Ethics
- Service

To help in this process, we have also attached documents that list Administration initiatives for the year 2000 and our State of the Union goals. Also, a sample and a blank template are attached so that each pillar can be summarized in a way that can be compared to others. The President will, of course, want back up memoranda describing each area summarized in the template. As you fill in the elements of your pillars, please include policies that are already being pursued. Andrew Mayock will e-mail the template to your office. If you have any questions, his number is 6 - 7492.

Once again, your assignments are due no later than 5 p.m. on Wednesday. The paper will be distributed for meetings that will be held on Thursday and Friday. Andrew will let you know in which meeting times your topic will be discussed.

Attachments: Clinton Administration Initiatives for the Year 2000
1997 State of the Union - Policies Announced
Sample Chart on Education Pillar
Template Pillar Chart (also will be provided electronically)

CLINTON ADMINISTRATION INITIATIVES FOR THE YEAR 2000

The following is a list, categorized by issue, of Clinton Administration goals, pledges, and programs geared for the year 2000. This list is comprehensive, but may not be exhaustive. There are likely to be other pledges we did not find on our first review.

Economy:

- Produce 8 million new homeowners by the year 2000. [Pres. Doc. 858, 6/12/97]
- Decrease welfare rolls by 2 million more people by the year 2000. [Pres. Doc. 136, 2/4/97]
- Move about a million more people from welfare to work by the year 2000. [Pres. Doc. 1698, 9/10/96].
- Eliminate all tariffs on computers, semiconductors, telecommunications equipment, and software products by the year 2000. [Pres. Doc. 2514, 12/16/96]

Education:

- Expand Head Start to one million children by 2002. [Pres. Doc. 13, 2/4/97]
- Hook up every classroom and library to the Internet by the year 2000. [Pres. Doc. 903, 6/19/97]
- Double the number of full-time youth volunteers by the year 2000 by adding another 50,000 participants in AmeriCorps. [Pres. Doc. 607, 4/28/97]
- By the year 2000, every 8-year-old should be able to read on his or her own, every 12-year-old should be able to log on to the Internet, every 18-year-old should be able go on to college, and every adult should be able continue to learn for a lifetime and get the skills necessary to get good jobs. [Pres. Doc. 558, 4/20/97]
- Make 2 years of college just as universal as a high school diploma is today by the year 2000. [Pres. Doc. 558, 4/20/97]
- Increase by ten-fold the number of charter schools we have by the year 2000. [Pres. Doc. 290, 3/6/97]
- Expand work study so that one million students will be able to work their way through college by the year 2000. Have 100,000 of these new work-study students join our America Reads efforts to help make sure all our 8-year-olds can read independently by the year 2000. [Pres. Doc. 230, 2/24/97]
- Erase American illiteracy by the year 2000. [Pres. Doc. 1242, 7/2/93]
- Increase the high school graduation rate to at least 90 percent by the year 2000 [Pres. Doc. Pg. 195, 2/3/94].
- Goals 2000. By the year 2000, the United States should meet the National Education Goals which include: All children in America will start school ready to learn; the high school graduation rate will increase to at least 90 percent; all students will leave grades 4, 8, and 12 having demonstrated competency over challenging subject matter including English, mathematics, science, foreign languages, civics and government, economics, the arts, history, and geography; every adult American will be literate and will possess the knowledge and skills necessary to compete in a global economy and exercise the rights and responsibilities of citizenship; every school in the United States will be free of drugs, violence, and the unauthorized presence of firearms and alcohol and will offer a disciplined environment conducive to learning. [Education Department, Goals 2000 Progress Report, Spring 1995]

Crime and Drugs:

- Put 100,000 more police on the streets of America's communities by the year 2000. [Pres. Doc. 1935, 9/30/96]
- By the year 2000, make every school in America free of drugs and violence. [Pres. Doc. Pg. 195, 2/3/94]
- Ensure that all state prisoners serve at least 85 percent of their sentences by the year 2000. [News & Record (Greensboro, NC), 9/22/96]

Environment:

- Clean up 900 Superfund sites by the year 2000. [Pres. Doc. 846, 6/9/97]
- Clean up two-thirds of the existing toxic waste sites by the year 2000. [Pres. Doc. 2379, 11/12/96]
- Devote $70 million to a total of 35 States to help them get safe running water for their people by the year 2000. [Pres. Doc. 1258, 7/16/96]
- Cut greenhouse gases to 1990 levels by the year 2000. [Pres. Doc. 865, 4/21/94]
- "I want an America in the year 2000 where no child should have to live near a toxic waste dump, where no parent should have to worry about the safety of a child's glass of water, and no neighborhood should be put in harm's way by pollution from a nearby factory. Today, I am calling for a new national commitment to help protect all communities from toxics by the year 2000." [Pres. Doc. 1567, 8/28/96]

Healthcare:

- Extend health coverage to as many as 5 million children by the year 2000. [Pres. Doc. 531, 4/17/97]
- Makes vaccines affordable for families and improve immunization outreach, with the goal that 90 percent of all two-year-olds should be fully vaccinated by the year 2000. [Pres. Doc.; Pg. 2009, 10/7/96]
- Wipe out polio by the year 2000. [Pres. Doc. 668, 4/17/96]

Immigration:

- Modernize our border crossing so that by the year 2000, 22 pairs of towns will be equipped with remote video systems and new technologies to give them 24-hour service. [Pres. Doc. 479, 4/8/97]
- Reach the goal of having at least 7,000 agents protecting our borders by the year 2000. [Pres. Doc. 200, 2/7/95]

Defense/ Foreign Policy:

- Increases funding for weapons modernization 40 percent by the year 2000. [Pres. Doc. 1643, 9/3/96]
- Develop by the year 2000 a defensive system that protects America from the threat of a long-range missile attack by a rogue state. The President said this system should be deployed by 2003. [Pres. Doc. 910, 5/22/96]
- Agree with Russia to stop plutonium production by the year 2000. [Pres. Doc. 1862, 9/26/94]
- Close Chernobyl by the year 2000. [Pres. Doc. 1097, 4/20/96]

The Boston Globe

WEDNESDAY, OCTOBER 8, 1997

Medicaid's outdated AIDS policy

Life expectancies for people infected with the AIDS virus continue to improve thanks to early detection and treatment with expensive new combination drug therapies using protease inhibitors. Recognizing this, the National Institutes of Health have issued new guidelines calling for earlier treatment of HIV infections. But the government's own requirements for Medicaid coverage of AIDS conflict with these principles. It is time for the Clinton administration to make good on a promise to extend Medicaid coverage to eligible patients at the earliest stages of the disease.

Under current Medicaid regulations, patients are not eligible for coverage unless they meet low-income requirements *and* qualify for one of the disabilities covered by the federal government's Supplemental Security Income program. Early infection with HIV – the stage at which protease inhibitors are most effective – is not on the list. Rather, an infected individual must wait to develop full-blown AIDS to qualify for Medicaid. By that time the immune system is often compromised.

There is no question that expanding Medicaid so that more HIV-infected patients can get access to the protease inhibitors will be expensive. Costs range from $8,000 to $10,000 a year for the drugs alone, and many thousands more people would qualify. But dollars spent up front on these medicines save enormous sums down the line in hospitalization. Medicaid coverage varies from state to state, but at a minimum it should include the cost of the drugs, lab tests, and support services needed to maintain the strict drug regimen; primary care to avoid simple infections that can be life-threatening; and substance-abuse treatment, which accounts for increasing numbers of AIDS cases in the first place. A conference on access and ethics in the new AIDS landscape takes place at the Kennedy Library today.

In April, Vice President Gore ordered the Health Care Finance Administration to devise a plan to extend Medicaid to HIV-infected patients within 30 days. It shouldn't take so long for the bureaucracy to catch up with medical progress.

San Francisco Chronicle

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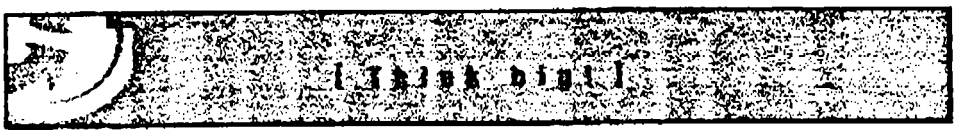

EDITORIAL -- `Hit Hard, Hit Early' With AIDS Treatments

DISMAYING AS the results are of a study showing that new AIDS drugs fail more than half of those who take them, there is nevertheless important, hopeful information in the report that especially deserves the attention of government health officials especially.

The major finding in a study of 136 patients at the San Francisco General Hospital AIDS clinic was that the much-heralded protease inhibitor drugs do not succeed in suppressing the disease more than half of the time. However, if the drug therapy is started early in the life of the disease, failure rates dropped to 10 to 20 percent.

``Our data supports the `hit hard, hit early' philosophy recommended by different panels of experts,'' said Dr. Steven Deeks of the University of California at San Francisco. ``Treatment should begin before the patient's T-cells drop to low levels.''

Hopefully, Secretary of Health and Human Services Donna Shalala and her crew are listening. At the request of Vice President Al Gore , Shalala's department supposedly is studying the feasibility of expanding Medicaid (Medi-Cal in California) coverage to include low-income people who have been diagnosed with AIDs but who do not show any symptoms. Such coverage would allow many people who cannot now afford the annual $8,000 to $16,000 cost of the drugs to obtain them. Under current law, AIDS patients must be considered disabled -- which essentially means they are already severely ill -- before they qualify for Medicaid coverage. Unfortunately, there are no signs that Shalala has put a priority on Gore's recommendation. The San Francisco study, however, should help the vice president put pressure on the department to take action. It makes sense that over the long term, the government would pay no more by providing early treatment since many people would be able to continue working and at the least delay the time they would have to seek government help for more expensive hospital treatment.

California lawmakers already have officially recognized the benefits of government-paid early treatment. The Legislature sent to Governor Wilson a bill (SB 1035 by Senator Richard Polanco, D-Los Angeles) that would require state health officials to respond within 90 days when and if the federal government finally does send out notification that Medi-Cal may be used by low-income people who have been diagnosed with the AIDS virus but who do not yet show symptoms of the disease.

The Boston Globe

WEDNESDAY, OCTOBER 8, 1997

Medicaid's outdated AIDS policy

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There is no question that expanding Medicaid so that more HIV-infected patients can get access to the protease inhibitors will be expensive: Costs range from $8,000 to $10,000 a year for the drugs alone, and many thousands more people would qualify. But dollars spent up front on these medicines save enormous sums down the line in hospitalization. Medicaid coverage varies from state to state, but at a minimum it should include the cost of the drugs, lab tests, and support services needed to maintain the strict drug regimen; primary care to avoid simple infections that can be life-threatening; and substance-abuse treatment, which accounts for increasing numbers of AIDS cases in the first place. A conference on access and ethics in the new AIDS landscape takes place at the Kennedy Library today.

In April, Vice President Gore ordered the Health Care Finance Administration to devise a plan to extend Medicaid to HIV-infected patients within 30 days. It shouldn't take so long for the bureaucracy to catch up with medical progress.

NAPWA

NATIONAL ASSOCIATION OF PEOPLE WITH AIDS

February 20, 1998

Sandra Thurman
Director
White House Office of National AIDS Policy
808 17th Street, NW, Suite 820
Washington, DC 20006

Ms. Thurman:

Enclosed, please find a copy of NAPWA's comments to Trish Riley of the National Academy for State Health Policy on the **Draft Standards and Guidelines for Review of Medicare and Medicaid Managed Care Organizations** produced as part of the **Quality Improvement System for Managed Care (QISMC) Initiative** for review.

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Washington D.C. 20005
Phone: (202) 898-0414
FAX: (202) 898-0435

February 11, 1998

Trish Riley
Executive Director
National Academy for State Health Policy
50 Monument Square
Suite 502
Portland, ME 04101

Dear Ms. Riley: Trish

NAPWA

NATIONAL ASSOCIATION OF PEOPLE WITH AIDS

I am writing to provide you with comments on the **Draft Standards and Guidelines for Review of Medicare and Medicaid Managed Care Organizations** produced as part of the **Quality Improvement System for Managed Care (QISMC) Initiative**. These comments are provided from the perspective of the National Association of People with AIDS (NAPWA). NAPWA serves as a national voice for the needs and concerns of people living with HIV disease throughout the United States. These comments should be viewed as supplementary to those submitted by the Consortium for Citizens with Disabilities (CCD), of which NAPWA is an active member. Whereas CCD's comments reflect the views of people with disabilities generally, NAPWA's comments will attempt to highlight concerns of particular importance to people living with HIV.

NAPWA was gratified to learn of the role that the National Academy is playing in coordinating comments from the public on these draft standards. Through our previous work together, we recognize that you have significant knowledge of the challenges in providing high quality health care to people living with HIV.

As a starting point for any comments on quality of care within Medicaid and Medicare, NAPWA believes it is important to understand the incredible importance of Medicaid and Medicare to HIV care. Indeed, through *Lay of the Land: What Program Managers Need to Know to Serve People with HIV/AIDS in Medicaid Managed Care* (a publication of the National Academy), we know that the Health Care Financing Administration (HCFA) estimates that Medicaid provides approximately $3.5 billion annually for HIV/AIDS care and Medicare provides approximately $1.4 billion annually in HIV/AIDS care. Other studies have indicated that more than half of all adults with AIDS and more than ninety percent of children with HIV infection depend on Medicaid for their health care. Medicare is the next single largest source of HIV/AIDS care in the United States. Clearly, these two programs, together, are the dominant purchasers of HIV/AIDS health care services and represent the cornerstone of our nation's response to the HIV epidemic.

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It is also important to understand that HIV care is extremely complex, the state of the art HIV therapy is changing very rapidly, and recent technological advances have fundamentally changed the landscape of HIV health care delivery. In November 1997, the U.S. Department of Health and Human Services and the Henry J. Kaiser Family Foundation promulgated *Guidelines for the Use of Antiretroviral Agents in HIV-infected Adults and Adolescents*. These guidelines were developed through the Panel on Clinical Practices for the Treatment of HIV Infection which brought together many of our nation's leading scientists, federal officials, and consumer advocates. These guidelines serve as a consensus statement on the most appropriate options in the treatment for people living with HIV. In recent years, therapeutic combinations of protease inhibitors, nucleoside reverse transcriptase inhibitors (NRTIs), and non-nucleoside reverse transcriptase inhibitors (NNRTIs) [all different classes of antiretroviral medications] have demonstrated a remarkable ability to slow and even stop HIV disease progression. While these medications are not effective for all who take them, many people have experienced spectacular transformations in their overall health as a result of these drugs. Epidemiologists tracking the HIV epidemic are also beginning to see declines in HIV mortality throughout the United States and in all racial and ethnic groups for the first time since the beginning of the HIV epidemic.

Unfortunately, access to these medications is complicated by their relatively high cost. Annual costs for combination therapy for an HIV-infected person is in the range of $12,000. What many people living with HIV fear is that as Medicaid transitions to managed care, their access to these medications will be restricted--either through being denied drugs completely or through formulary restrictions which could have life-or-death consequences on the ability of people to benefit from HIV drug therapies now or in the future if they are not given access to the full range of approved drugs. To date, empirical data suggests that access to these medications is uneven. Many people have been provided access to these life-sustaining treatments, but too many do not have access. Further, access to treatment within Medicaid appears to be vary dramatically across lines of race, geography and gender. This is complicated by competing impulses on the part of health plans. In some cases, capitated financing structures create powerful incentives to provide these treatments as a means of lowering hospital and other expenses. In other cases, the financing structure creates incentives to stringently limit access to these treatments as a means of reducing short-term expenses. Financing systems have a profound effect on health care quality. In the Medicare context, we believe that an important goal of the new Medicare Choice program must be to create incentives for health plans to offer prescription drug benefits--including the full range of FDA-approved medications.

We applaud HCFA for striving to move the issue of quality improvement forward. From the perspective of people living with HIV, however, no quality improvement strategy is acceptable unless a primary goal involves establishing concrete, enforceable standards that will help to ensure that all people living with HIV in the Medicaid and Medicare programs know their HIV serostatus and are provided access to these life-saving treatments. We believe it is an appropriate goal of HCFA's quality improvement efforts to ensure access to what is a federally sanctioned standard of

care for HIV therapy. In order to develop a mechanism for making meaningful improvements in the quality of care for people living with HIV, the complexity of HIV care and the rapid pace of change in what constitutes state-of-the-art treatment must be addressed. Further, the difficulties in establishing standards that may qickly change cannot preclude the establishment of enforceable standards to guide health plans in structuring their programs, enable consumers to compare the performance of plans, and provide HCFA and the states with data with which to demand accountability from health plans.

From this brief discussion of HIV therapy, we also believe that delivering health care to people living with HIV is exceedingly complex. We are troubled that inadequate input has been sought from Medicaid and Medicare consumers with HIV (or their representatives). When we reviewed the QISMC Quality of Care Group and the QISMC Behavioral Health Panel, we recognized several people who have extensive expertise in health policy, but we did not see persons who are identified as either experts on HIV care (or the care of people with disabilities generally). Beyond mere knowledge of the complexities of these core beneficiary groups, NAPWA believes it is essential that individuals be brought into the QISMC process who are identified as liaisons with consumers and consumer advocates. Some of these liaisons must be persons who have credibility within the disability community.

Having reviewed the Draft Guidelines, NAPWA is pleased that HCFA has undertaken this effort to improve quality. Nonetheless, we are deeply concerned that the end result of these proposed guidelines, if implemented as proposed, would not be an improvement in the quality of care for people living with HIV. Without radical modifications, NAPWA would oppose the implementation of these draft guidelines. We would like to make the following four recommendations for moving forward:

Reconstitute and Reconvene the QISMC Quality of Care Group and the QISMC Behavioral Health Panel.

As discussed, we believe many complex issues have not been adequately discussed. Further, people with disabilities, a core beneficiary group in both Medicaid and Medicare, have not been appropriately involved in the development of these draft guidelines. In particular, NAPWA requests that representatives of the HIV community be involved on both of these QISMC Panels.

Coordinate the QISMC Process with the HHS Review of the Consumer Bill of Rights and Responsibilities(CBRR).

While we appreciate that HCFA is attempting to move forward expeditiously with the implementation of a quality improvement system, we do not believe that these proposed guidelines live up to the spirit of the CBRR. NAPWA requests that HCFA more closely coordinate with the CBRR and the work of the Presidential Advisory Commission on Consumer Protection and Quality in the Health Care Industry.

Establish concrete and enforceable standards as a floor to monitor the performance of all managed care plans in Medicaid and Medicare.

A primary criticism of the proposed guidelines is that a plan could appear to be making significant improvements in quality under these guidelines, yet still be providing abominable care to vulnerable beneficiaries. Further, the structure of the guidelines would make it impossible to compare among plans. For this reason, NAPWA believes that all managed care plans must be required to perform up to a minimal level. If performance is substandard, sanctions must be applied. We believe that what would constitute this performance floor is complex and beyond our capacity to comment here. NAPWA welcomes the opportunity to continue a dialogue with the National Academy or HCFA on how such a floor should be structured.

Implement the Draft Guidelines as a Supplemental Quality Improvement Strategy.

NAPWA does not reject the merits of many of the quality improvement ideas contained within these guidelines. We further recognize that variations in the types of enrollees and variations in the health status of enrollees make it appropriate to encourage plans to undertake quality improvement activities that are tailored to their unique circumstances. Therefore, we propose that these guidelines be recast as a required, but supplementary quality improvement activity that is in addition to efforts to mandate that all plans meet basic performance standards.

Quality improvement in managed care is an incredibly important issue for people living with HIV. As you review comments on these draft guidelines, NAPWA remains committed to working with you and HCFA to ensure that a reasonable and effective quality improvement system for managed care is developed.

Sincerely,

Jeffrey S. Crowley, M.P.H.
Deputy Executive Director for Programs

cc: Ms. Nancy Ann Min DeParle
Ms. Sandra Thurman

Consortium for Citizens with Disabilities

Kathy McGinley 202-785-3388
Jeff Crowley 202-898-0414
Bob Griss 202-842-4408

February 11, 1998

Ms. Trish Riley
Executive Director
National Academy for State Health Policy
50 Monument Square
Suite 502
Portland, ME 04101

Dear Ms. Riley:

We are writing on behalf of the Health Task Force of the Consortium for Citizens with Disabilities (CCD). CCD is a Washington-based coalition of nearly 100 national disability organizations that advocate with and on behalf of children and adults with disabilities and their families. CCD member organizations represent the broad spectrum of disabilities including both mental and physical impairments. We are writing to provide comments on **Draft Standards and Guidelines for Review of Medicaid and Medicare Managed Care Organizations**. These CCD Health Task Force comments reflect overarching concerns that we have with QISMC specific to the health related needs of children and adults with disabilities and chronic illness and their families. Individual disability organizations will be providing comments specific to their areas of expertise.

Due to their health and disability status, the children and adults that we represent are disproportionately represented within the Medicaid and Medicare programs. Indeed, in both of these programs, people with disabilities are those beneficiaries with the most extensive health care needs--and persons for whom the consistent provision of high-quality health care has proven most challenging. CCD is firmly committed to ensuring that as both of these programs are transformed by managed care, cost containment strategies will not be used to justify substandard or inappropriate care. At the same time, we firmly believe that any "quality measures" developed for public sector managed care programs will – in the long run – have an impact on health plans in the private insurance market. Therefore, our concerns relate to the quality of health generally for people with disabilities.

Many of our member organizations have a long history of working with the National Academy for State Health Policy. We believe that your organization is an appropriate mediator in the effort to craft a quality improvement approach that recognizes the varying needs and divergent circumstances of health plans providing care to Medicaid and Medicare beneficiaries -- yet which firmly demands that the significant public resources devoted to these costly health care

programs are not wasted – while ensuring that all beneficiaries will have access to high quality health care.

Having reviewed the draft guidelines, CCD recognizes some merit to the approach taken to quality improvement. **We are particularly pleased with the Chapters on Enrollee Rights and Health Services Management. However, we find that the Draft does not clearly demonstrate how these two strong sections correlate with the Quality Assessment and Performance Improvement (QAPI) mechanism that makes up the bulk of this Draft. Therefore, the CCD Health Task Force deeply concerned that this approach, in isolation, will not lead to an improvement in health care quality and will not protect the most vulnerable beneficiaries within Medicaid and Medicare. Without substantial augmentations, we could not support the implementation of these guidelines**

The CCD finds it odd that the draft for HCFA's QISMC is proposed as a framework for a *uniform set of quality standards* to be used by HCFA and states for managed care organizations contracting with Medicare and Medicaid – then it allows a managed care *plan to select its own particular topics for measurement and improvement.*

To its credit, QISMC recognizes that measuring and improving outcomes is the primary purpose of health care, that reliable and valid process measures are only relevant as "proxies for outcomes", and that managed care plans should be able to document changes in "enrollee health, functional status, or satisfaction" across a broad spectrum of care and services, as a result of quality improvement activities. QISMC proposes an enlightened set of quality standards for Medicaid and Medicare managed care plans, along with an extremely flexible set of quality improvement activities that could be used to improve health outcomes.

However, there is nothing uniform about the quality standards that QISMC requires, and minimum performance levels must be established by contractual obligations between HCFA or the State Medicaid agencies and each managed care plan. The problem with this arrangement is that both HCFA and State Medicaid agencies are sometimes more interested in limiting their costs *as purchasers* than insisting on quality standards *as regulators* of managed care plans which are often reluctant to serve higher cost patients without risk adjusted premiums. That is why it is crucial that quality standards, especially for persons with disabilities, are put in the context of compliance with federal civil rights law, based on the Americans with Disabilities Act (ADA) and Section 504 of the Rehabilitation Act, which requires that managed care plans ensure that persons with disabilities have an "*equal opportunity to benefit*" from covered services as non-disabled enrollees.

We are concerned that the Draft indicates that the decision was made to release this document prior to a full analysis of either the measures included in the Consumer Bill of Rights and Responsibilities (BORR) and the requirements of the Balanced Budget Act (BBA). The CCD questions this decision since the Secretary will be releasing a report this month on the steps that the Department will take to implement the recommendations in the BORR. We believe that taking the time now to compare the BORR and this draft would save time in the long run and help avoid the need for changes in the future. We also question your decision to release this draft before comparing it with the quality-related provisions of the Balanced Budget Act (BBA).

The CCD understands that HCFA would like to use QISMC as the basis for quality guidelines that were mandated in the BBA and we are extremely concerned with the apparent effort by HCFA to make this product fit the mandate of the BBA without the careful consideration of the Congressional intent which led to the quality guidelines provisions in the BBA. It is obviously necessary to fulfilling the intent of the law that there be a full analysis of the BBA provisions on hand before this draft is revised and used as the basis for proposed regulations.

The CCD protests the short time frame permitted for comments on this document which could play a major role in formulating how services available under both Medicare and Medicaid will be evaluated for quality, and – in the long run – how quality improvement is measured in the private sector. The CCD represents people with disabilities -- some of the most vulnerable individuals in the nation -- and -- the group with the least amount of research currently available related to quality standards. Therefore, quality issues are some of the most important issues with which we deal. According to the cover of the draft, this document was released on Dec. 22, 1997. Unfortunately, those disability organizations that did receive a copy of the draft received it in the last few weeks of January, without the benefit as we understand of an intended 30 day comment period. Therefore, a Feb. 11 deadline for comments is unacceptable.

We are also extremely concerned with the under-representation of disability advocates on the QISMC Quality of Care Group, and amazingly also on the QISMC Behavioral Health Panel. The CCD asserts that the involvement of consumers with disabilities or their representatives is essential if quality measures are to really measure what is important to consumers. As many of our member organizations will also indicate, consumer involvement in quality should not begin and end with the evaluation of data regarding a particular plan. Consumers and their representatives are essential stakeholders. As members of the target populations for proposed QAPI clinical and non-clinical focus areas, consumers should have input on decision making bodies, not merely advisory bodies, regarding the design, implementation, evaluation, and enforcement of any quality improvement process. Enrollee involvement is necessary for all aspects of the development and implementation of quality management.

While the measures included in the Draft may help reflect quality related to clinical and even some functional outcomes, they in no way measure the personal outcomes that are of such importance to people with disabilities. For example, a plan may be able to measure how many visits to a certain provider a person has as well as the fact that this helps that person improve or maintain his mobility. However, these types of measures do not demonstrate if any of this helps that person attain a desired level of autonomy, or even more simply, helps him be able to leave his home and find a job.

According to the draft, the QISMC initiative builds on a variety of HCFA and State Medicaid agency efforts in recent years to promote the assessment and improvement of quality in organizations contracting with Medicare and Medicaid. While this may be good news for the non-disabled population, it is not for those with disabilities. For the most part, the majority of children and adults with disabilities have not been part of state Medicaid managed care programs. In fact, as stated in the 1996 Government Accounting Office Report, *Medicaid Managed Care: Serving the Disabled Challenges State Programs*, states have faced great difficulty in their attempts to design a managed care program that meets the needs of people with

disabilities. This lack of participation leads to a dearth of knowledge on which to build any evaluative measures. In addition, in those situations where people with disabilities have been included in managed care, their numbers are often so small that they are not part of the "standard" measures.

Some states have moved more quickly to enroll individuals with mental disabilities in managed care arrangements--almost always using carve-out strategies and contracting with one or more behavioral health care entity. Experience with these contracts, which now cover about one third of Medicaid recipients who have serious mental illness, shows very mixed results. In only a very few states do the arrangements seem to working very well, in another few states they have been close to disastrous. In the majority, there are significant problems, especially during start-up periods.

The most important lessons which can be learned from this experience--before moving the larger population of persons with disabilities into managed care is--(1) take the time to learn how to contract for system-wide management from the experience of the states which have already done it; (2) engage the consumer stakeholders in the process from the very beginning in a decision-making and not solely advisory capacity; and (3) do not plan substantial, if any, cuts in spending until the program is up and running and savings can actually be realized (initial savings should be reinvested in expanding low cost community-based options to ensure a meaningful system of care).

The BBA standards, which HCFA is to publish this summer based, apparently, on QISMC should take these lessons into account and should build on state experiences with managed care for persons with disabilities. To accomplish that goal, they will have to be far more specific than QISMC. QISMC identifies areas of concern, but it then provides little guidance on appropriate policies or approaches. As such it will be of little help to states and the data that results from these improvements may be of even less value to consumers looking to HCFA for protections of their rights and interests. There should also be a heavy emphasis on involving consumers, people with disabilities and their families in the planning, and monitoring of public sector managed care plans.

For all these reasons and for the additional concerns included in the comments which follow, the CCD Health Task Force recommends a separate and distinct set of criteria for Medicaid and Medicare managed care plans which will enroll people with disabilities or which are targeted specifically to people with disabilities. Experience with the carve-out plans for populations of children and adults with mental illness have clearly demonstrated how different the issues are and how poorly standard managed care arrangements adapt to persons with ongoing and complex health care needs. A separate section on plans serving persons with disabilities could then deal adequately with their particular needs, and could reference appropriate outcome and performance measures (such as the Center for Mental Health Services Report Card or the AMBHA PERMS).

In addition to the BBA requirement of quality standards for managed care, the law also included a provision mandating a study of the special needs of individuals with disabilities in managed care. If done accurately and in a timely manner, this study could provide extremely useful

information as quality standards and guidelines are developed. A few critical issues which should be targeted in this study include an appropriate definition of medical necessity, the effective use of risk adjustment, and ADA compliance.

The CCD and other representatives of children and adults with disabilities and their families look to Medicaid and Medicare for health and health related services that meet their needs. Many variables play a role in a high quality health care system. For individuals with disabilities and their families, access to needed services and supports can make the difference between living a more healthy independent life in the community or being unhealthy, dependent, and – in the worst case scenarios – institutionalized or dead. It is time for the state and the federal government to rethink their definition of "cost effectiveness" and their goal of cost-cutting with these simple facts in mind. This is why quality is such an important issue to people with disabilities.

If HCFA is really interested in ensuring that people have access to quality health care that meets their needs, then the CCD believes that it is time that HCFA "bite the bullet" and take a strong stand on what constitutes the core of a quality health care system. When HCFA does this, the CCD looks forward to working with them to ensure that this "core" includes those services and supports so critical to children and adults with disabilities.

It is obvious to the CCD and to many others that once you design a health care system that meets the needs of people with disabilities – you will have designed a system that will meet the needs of all those who are not disabled. Please call one of the CCD Health Task Force co-chairs listed at the top of page one if you have any questions.

Sincerely:

Jeff Crowley
NAPWA

Bob Griss
Center on Disability and Health

Kathy McGinley
The Arc

CCD Additional Specific Comments

The Establishment, Monitoring, and Enforcement of Quality Standards

The CCD is extremely concerned with the "permissible" quality of these Standards. We believe that we need a strong system of quality assurance – meaning that the services available meet the needs of the consumers to the greatest degree possible and provide consumers with the information they need to make informed choices. We do not believe that QISMC offers this. Instead, it is a system of quality improvement – and one that, unfortunately, allows the health plans to determine just what they want to improve. For example the statement that the quality standards...*do not specify the particular measures for which reporting will be required or the minimum performance levels that organizations will be expected to achieve. These specifications would be developed as part of the negotiations*.... When these types of decisions are left up to health plans – **the majority of which have little knowledge of the range of needs of people with disabilities and have little or no consumer representation on their policy making boards, it causes disability advocates grave concern**. QISMC does not recognize the important contributions which consumers with disabilities can make to improving practice guidelines, to identifying barriers to access to quality care in managed care plans, and to advocating for quality issues as participants on the Board of Directors of managed care plans.

The exact status of the Guidelines which accompany the Standards is also unclear. HCFA makes clear that the Guidelines interpret the Standards, but implies that they have no force whatsoever and will not even be used as a monitoring tool. Yet many important issues are dealt with in the Guidelines, while the corresponding Standard is very inadequate. The CCD strongly believes that a "toothless" quality system with so much of the decision making left up to the plans is unacceptable.

While the CCD does not dispute the affect of the BBA, as presented, we do wish to remind HCFA that the Congress has not repealed the Medicaid and Medicare statutes. HCFA still has a statutorily mandated role to play in assuring that these federal programs are of high quality. HCFA's role and the role of the states establishing, monitoring, and enforcing quality standards cannot be abrogated to health plans. We believe that any effective quality assurance system must include a clear cut and strictly enforced system of incentives and sanctions. Incentives for those plans that do an exceptional job at providing high quality care, and sanctions, including financial penalties or denial of participation, for those plans that do a poor job. The CCD believes that this type of well structured and clearly defined system would also appeal to good health plans by ensuring that those who do well benefit and by removing those who do not from the market.

The CCD believes that external oversight is required to ensure that persons with disabilities are not discriminated against by being subjected to criteria and methods of administration in managed care plans which deprive them of "equal opportunities to benefit" from covered services. Such administrative mechanisms include: restrictive definitions of medical necessity, utilization review criteria which reflect the health care needs of the general population rather than persons with disabilities, economic profiling criteria that penalize providers who provide appropriate care to

persons with disabilities, and arbitrary limits in the benefit package which deprive persons with disabilities from receiving the same benefit as persons without disabilities. HCFA needs to develop regulatory initiatives in these areas to promote quality and consumer protection as it has with the anti-gag rule policy, regulation of physician incentive arrangements, and Medicare rules for expedited appeals of adverse coverage decisions

A number of assumptions are made in this Draft which cause the CCD great concern. These include the assumption that rigorous measurement and monitoring of health plan actions are currently ongoing. While it may be true that some plans do make this effort, we do not believe that this is generally the case. The Draft also draws attention to purchasers who have undertaken their own initiatives to improve quality in organizations serving the commercial population and the fact that many employers and cooperative purchasing groups and some states are requiring accreditation by some entity, such as NCQA. Unfortunately, the majority of these accrediting entities do not include quality measures based on the needs of children or adults with disabilities.

The Draft states that *in adopting minimum performance measures, it will clearly be important for HCFA and states to assure that the targets are achievable, meaningful and equitable. Requirements would be established only for measures for which a valid baseline exists, that is for which there are sufficient data to allow comparison... among organizations with similar populations.* Currently, there are not sufficient outcome measures for people with disabilities. In addition, there are not enough people with disabilities in the general beneficiary pool in most cases. How long will it take to establish baseline data for people with disabilities and is it a priority of HCFA?

HCFA reports that HEDIS was the basis for much of this Draft. For the CCD and people with disabilities, this is one more red flag. HEDIS in no way reflects the needs of people with disabilities. In fact, the CCD is concerned that efforts to instill a disability perspective in HEDIS have been ignored. HEDIS 3.0 includes functional measures for senior citizens which could be equally useful for individuals with disabilities – however, they are not applied to them. In addition, while there are NCQA accreditation standards for behavioral health care, they are very targeted to private sector clients and private sector issues. An analysis published by the Bazelon Center for Mental Health Law found a number of shortcomings in the NCQA standards with respect to consumer involvement, public information, continuity of care, special populations, children's issues, informing purchasers, corrective actions, and delegation of responsibilities. The analysis also provided 29 suggestions to improve the standards for those public purchasers interested in using them.

<u>The Importance of an Appropriate Standardized Definition of Medical Necessity</u>

The Standards do not define or provide any guidance with respect to the definition of *medical necessity* in the Medicaid context. The Medicaid statute and case law make clear that this term is to be broadly interpreted to encompass a wide range of clinical services and health-related support services which are particularly important for persons with disabilities. Furthermore, the benefit package must include all mandatory Medicaid services for adults and all Medicaid-covered services for children screened through EPSDT. No set of standards for Medicaid

managed care should omit a discussion of what is an appropriate medical necessity definition in the Medicaid context.

The CCD strongly believes that the most important building blocks of a high quality health care system is a broad standardized definition of "medical necessity". For individuals with disabilities, the definition of medical necessity used by a health plan or insurer is often the key to independence or dependence. The CCD strongly believes that HCFA should establish a uniform definition of medical necessity as opposed to allowing plans to determine the process.

The CCD believes that a federal definition of medical necessity should require plans to cover services which are: 1) calculated to prevent, diagnose, correct, cure, alleviate, maintain or preclude deterioration of a physical or mental condition that threatens life, causes pain or suffering, or results in illness, disability or infirmity; 2) individualized, specific, and consistent with symptoms or confirmed diagnosis of the illness, disability or injury under treatment, and not in excess of the patient's needs; 3) necessary and consistent with generally accepted professional medical standards as determined by the Secretary of Health and Human Services or the State Department of Health and; 4) reflective of the level of service that can be safely provided, and for which no equally effective treatment is available. While medical necessity should be consistent in type, frequency and duration of treatment with scientifically based national guidelines, managed care plans should have financial incentives to improve clinical and functional outcomes.

From a disability perspective, it is crucial that the definition of medical necessity recognizes functional deterioration. It is also important that the plan be prohibited from denying medically necessary covered services that are expected to produce a clinical or functional benefit on the basis of cost-effectiveness. Moreover, utilization review criteria should not deprive enrollees with certain conditions from receiving equal access to quality care. HCFA should require States to identify plans that have patterns of denying equal access to quality care for all enrollees and take appropriate corrective action.

There cannot only be paper adherence to a strong definition of medical necessity. Because the contract and definition of medical necessity are what determine what the plan is legally obligated to provide, the states decidedly have the motivation to ensure that plans live up to what is available – at least in the Medicaid program – in the state Medicaid plan. If states enter into contracts that are deficient, the responsibility to provide these services rests directly with the states..

<u>Quality Assessment and Performance Improvement (QUPI) Focus Areas</u>

This is another area of major concern to the CCD. The Draft states that *projects conducted under the organization's QAPI program address and achieve improvement in major focus areas of clinical care and non-clinical services*. While this may appear to be a reasonable approach on first reading, it soon becomes apparent that **this is one of the most dangerous areas for individuals with disabilities.** Once again, health plans have control of the system and are permitted to determine what areas they are going to target and at what time during a phase in period.

The CCD strongly believes that **all six of the Non-Clinical Focus Areas are important. In fact, these are some of the basis non-clinical components of a good health plan. It is for this reason that we strongly recommend that all plans be required to demonstrate expertise in these areas before they are certified by either Medicaid or Medicare**. There is no reason why any one of these critical components should be allowed to be phased-in over a three year span of time.

The Clinical Focus Areas identified are also each important. However, once again it is the phase-in period which we must strongly protest. The CCD strongly believes that this phase-in system will permit plans to continue to ignore the needs of individuals with disabilities. Children and adults with high health care needs have not been the favorites of managed care systems that are designed solely to cut costs. Unfortunately, almost one-half of the Medicaid Clinical Focus Areas represent higher cost populations. Under this scheme, Medicaid managed care plans would have to demonstrate "improvement" in all of the areas beginning only in the third year. Currently, health plan contracts commonly run for less than three years. Therefore, it is almost assured that plans will begin with the easiest and least costly focus areas such as prevention for adults, pre-natal, well child care, and ambulatory care for children and families. This will leave the more difficult focus areas such as chronic disease for the elderly or disabled, mental health services, substance abuse services, and services for people with developmental disabilities for the end. It appears to the CCD that this structure will lead to several things: 1) plans will not be required to demonstrate competence in these more difficult areas because the contract will run out before they need to; 2) plans will never include these services or these populations because the number of focus areas for improvement can *be reduced if organization's Medicaid contract does not include services or population addressed in a clinical focus area.*

Managed care plans should be required to focus on quality improvement activities for various disabilities such as children, working-age persons, and seniors with physical impairments, mental illness, cognitive disabilities, and sensory impairments. The current proposed phase-in strategy for QISMC will not require managed care plans to focus on comparable conditions that can lead to generalizable strategies in other managed care plans. By requiring managed care plans to report on quality improvement efforts and outcomes for persons with different categories of disabilities, it will be easier to develop the valid data base on quality benchmarks that does not exist for many low prevalence conditions.

Deeming

"Deeming" procedures based on private accreditation criteria that do not reflect the capacity of managed care plans to improve outcomes for persons with disabilities will allow managed care plans to avoid quality assurance for persons with disabilities under the guise of avoiding duplication of oversight. QISMC provides a great rationale for minimum quality standards to ensure that managed care plans have sufficient provider capacity to meet the needs of *all* its enrollees, including *the needs of enrollees who require rarely used services or have infrequently encountered problems,* but then makes the unwarranted assumption that appropriate standards are already measured by independent accrediting bodies or state regulators, and that these are not problems for managed care

plans *that are already serving commercial populations*. The loopholes written into the BBA for quality assurance in Medicare managed care plans that would exempt them from QIO review if they have an *excellent record* in quality assurance makes a mockery of the minimum quality standards for all enrollees, such as persons with disabilities.

Other Issues

The CCD has concerns with the statement in the Draft that "*this obligation (to assure beneficiaries that every organization offered to them meets some basic quality standards) is owed, not just to beneficiaries, but also to taxpayers*". It is our assertion that the majority of these beneficiaries or their families are taxpayers. In addition, access to quality health care and supports and services helps ensure healthier and more independent citizens. This result should please everyone. We strongly agree that the government should get what it pays for. Therefore, the government should only pay for a high quality health care system that meets the needs of all its members.

As indicated previously, the CCD is pleased with the Enrollee Rights in Chapter Two and with the Health Services Management procedures in Chapter Three. However, we are concerned with how these rights and procedures would be functionalized in a system that is built around QAPI activities. The CCD seeks strong and enforceable federal quality standards that are developed with consumer input and with a clear view as to what "quality" really means to people with disabilities.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Health Care Financing Administration

7500 SECURITY BOULEVARD
BALTIMORE MD 21244-1850

January 21, 1998

Dear Colleague:

This is the document to which we referred in our letter of January 20,1998. It is, as you will see, about the Quality Improvement System for Managed Care (QISMC) which will be discussed at the briefing from 1:00 to 4:00 PM, on January 30, 1998, in Room 5169 of the Cohen Building. Our earlier letter contains the details.

We look forward to seeing you there. If you have any questions, please call Tim Keating on (410)786-3198, or Carol Sampson on (410)786-3210.

Sincerely,

Carol Sampson /for

Elisabeth Handley, Director
Partnership Development Group

NATIONAL ACADEMY
for STATE HEALTH POLICY

January 8, 1997

To: Interested Parties

From: Trish Riley

Re: Public Review of Draft Standards and Guidelines for Review of Medicaid and Medicare Managed Care Organizations

During the past year, the Health Care Financing Review Administration (HCFA) has been working with state and federal officials, beneficiary advocates, and the managed care industry in developing standards and guidelines to assure that managed care organizations contracting with Medicaid and Medicare protect and improve the health and satisfaction of enrolled beneficiaries. Known as the Quality Improvement System for Managed Care or QISMC, the goal of this initiative has been to develop a coordinated Medicaid and Medicare quality oversight system that could reduce duplicative or conflicting efforts. The National Academy for State Health Policy was contracted by HCFA to assist with this work and to facilitate a broad public review of the draft document.

We need your input at this time. Please review the draft standards and guidelines from your unique perspective and tell us how they can be improved. We are particularly interested in the alternatives you would propose to sections you find lacking. While we realize this review is a time-consuming assignment, your comments will help shape the final product.

All comments must be submitted via mail, fax or e-mail by February 11, 1998 to:

Trish Riley
National Academy for State Health Policy
50 Monument Square, Suite 502
Portland, ME 04101
Fax: 207-874-6524 * E-mail: info@nashp.org

Please let us hear from you on this important effort.

STANDARDS AND GUIDELINES FOR REVIEW OF MEDICARE AND MEDICAID MANAGED CARE ORGANIZATIONS

PUBLIC REVIEW DRAFT

Prepared for the Health Care Financing Administration as part of the Quality Improvement System for Managed Care (QISMC) Initiative

DECEMBER 22, 1997

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INTRODUCTION

The Quality Improvement System for Managed Care (QISMC) is a system for assuring that managed care organizations contracting with Medicare and Medicaid protect and improve the health and satisfaction of enrolled beneficiaries. (The term "organization" is used throughout this document to cover a variety of entities that serve Medicare or Medicaid beneficiaries on a risk basis through a network of employed or affiliated providers. The application of QISMC to different types of entities and contracts is considered in chapter 1.)

Under QISMC, a uniform set of quality standards will be used by HCFA and State Medicaid agencies in initial and ongoing determinations that an organization is eligible to enter into a Medicare or Medicaid contract. Each organization will:

- Operate an internal program of quality assessment and performance improvement that achieves demonstrable improvements in enrollee health, functional status, or satisfaction across a broad spectrum of care and services.

- Collect and report data reflecting its performance on standardized measures of health outcomes and enrollee satisfaction, and meet such minimum performance levels on these measures as may be established under its contract with HCFA or the State Medicaid agency.

- Demonstrate compliance with basic requirements for administrative structures and processes that promote quality of care and beneficiary protection.

This document provides an introduction to QISMC. It is in four parts.

Chapter 1 establishes a framework for understanding the QISMC requirements. It includes background on the origins and goals of QISMC; an examination of the roles of HCFA, States, and other participants in promoting quality; and an overview of the three basic approaches to assuring quality embodied in QISMC.

Chapter 2 sets forth the standards that each organization must meet under QISMC. The standards are grouped under four domains: quality assessment and performance improvement, enrollee rights, health services management, and delegation.

Chapter 3 provides guidelines to assist organizations, HCFA and State Medicaid agency reviewers, and other interested parties in interpreting the standards.

Chapter 4 outlines the process for implementing QISMC.

CHAPTER 1: FRAMEWORK OF QISMC

THE DEVELOPMENT OF QISMC

Origins and Goals of the QISMC Initiative

The QISMC initiative builds on a variety of HCFA and State Medicaid agency efforts in recent years to promote the assessment and improvement of quality in organizations contracting with Medicare and Medicaid. A partial list of these efforts would include:

1. The Quality Assurance Reform Initiative (QARI), which developed and tested standards for States to use in monitoring and improving quality in Medicaid contractors, with a particular emphasis on the organizations' own internal quality improvement efforts.

2. Initiatives to improve accountability by requiring uniform collection and reporting of data that will allow assessment of organization performance and facilitate comparisons among organizations.

   - HCFA now requires that Medicare contractors report all Medicare-relevant performance measures from the Health Plan Employer Data and Information Set (HEDIS 3.0) developed by the National Committee for Quality Assurance (NCQA).
   - HCFA has also worked with States and others to develop and implement Medicaid-specific HEDIS measures. Originally embodied in a separate Medicaid HEDIS, these measures have substantially been included in HEDIS 3.0. Many States are now requiring reporting by Medicaid contractors on some or all of the Medicaid measures.
   - HCFA and other purchasers are working together with consumer groups through the Foundation for Accountability (FACCT) to develop and test additional measures of health outcomes.
   - HCFA requires that Medicare contractors participate in an independently-administered Medicare beneficiary satisfaction survey, the Medicare version of the Consumer Assessments of Health Plans Study (Medicare CAHPS).

3. Projects to enhance the role of Medicare Quality Improvement Organizations (QIOs) in evaluating and improving managed care organization quality, including the development and testing of a minimum set of performance evaluation measures and quality improvement projects developed through collaboration between PROs and managed care organizations. States have undertaken similar efforts through Medicaid External Quality Review Organizations (EQROs).

4. Regulatory initiatives to promote quality and consumer protection, including the anti-gag rule policy to assure that beneficiaries have information about all the health care options appropriate for them; regulation of physician incentive arrangements; and new Medicare rules for expedited appeals of adverse coverage decisions by organizations.

At the same time, other purchasers have undertaken their own initiatives to improve quality in organizations serving the commercial population. Many employers and cooperative purchasing groups and some States are now requiring that organizations be accredited by NCQA, the Joint Commission on Accreditation of Healthcare Organizations, The American Healthcare Accreditational Commission (formerly known as URAC), or other independent bodies. Others are requiring that organizations report their performance on HEDIS, FACCT, or other measures and conduct enrollee surveys using the CAHPS or other instruments. There have also been heightened State regulatory efforts, through insurance or licensing requirements, including the development by the National Association of Insurance Commissioners (NAIC) of model acts on network adequacy, quality assessment and improvement, and utilization review.

The proliferation of new quality measurement and quality improvement techniques has occurred in the context of rapid growth in managed care enrollment; development of new managed care models, such as provider-sponsored plans and behavioral health and other specialized organizations; and mounting concern among consumers, advocates, and policymakers about the adequacy of existing safeguards and monitoring efforts.

The QISMC initiative was begun in 1996 with several basic goals:

- To clarify the responsibilities of HCFA and State Medicaid agencies in promoting quality, taking into account both their distinct roles as purchasers of services for vulnerable populations and the opportunities for partnership with other public and private quality improvement efforts;
- To develop a coordinated Medicare and Medicaid quality oversight system that would reduce duplicative or conflicting efforts and send a uniform message on quality to organizations and consumers;
- To make the most efficient use of available quality measurement and improvement tools, while allowing sufficient flexibility to incorporate new developments in the rapidly advancing state of the art.

To support the development of the QISMC, HCFA contracted with the National Academy for State Health Policy to convene a Quality of Care (QOC) group, made up of managed care organization representatives, State and Federal purchasers and regulators, and beneficiary advocates. A second group of experts in mental health and substance abuse services was convened separately to assure that the perspectives of providers and users of these services were appropriately considered in the QISMC process. (The membership of these groups is listed in appendix A.)

The Academy in turn subcontracted with the Institute of Health Policy Solutions to draft two documents that would form the basis for the QOC and behavioral health groups' discussions: a conceptual framework for a unified Medicare-Medicaid quality oversight system and a first draft of quality standards for organizations, along with interpretive guidelines for these standards.

The QOC and behavioral health groups' comments and recommendations on these initial documents highlighted key issues for consideration in HCFA's internal policy deliberations. These led to revisions, presentation of the revisions to the review groups, further comments and recommendations, and further rounds of revisions. This cyclical process has been invaluable in promoting HCFA's understanding of its role and that of State agencies, and in refining the basic standards and guidelines. It should be emphasized that, while HCFA has relied heavily on the insight and expertise of the review groups, the present draft of this document reflects policy decisions by HCFA and does not necessarily represent all of the views of the panels or of any of their individual participants.

Implications of the Balanced Budget Act

While the QISMC was under development, Congress enacted the Balanced Budget Act (BBA) of 1997. The BBA makes extensive changes in Medicare and Medicaid law relating to contracts with managed care organizations or other health plans. Medicare is authorized to contract with new types of plans, including provider-sponsored organizations, private fee-for-service plans, and MSA plans. Under Medicaid, States have been given greater flexibility to enter into managed care arrangements without waivers. At the same time, the BBA establishes new quality and consumer protection standards for both Medicare and Medicaid contracts.

The BBA affects QISMC in several key ways.

1. QISMC deliberations focused chiefly on assuring quality in the types of entities that most frequently contract with HCFA and States under current law—that is, TEFRA risk HMOs under Medicare and risk-comprehensive contractors under Medicaid. The BBA requires an evaluation of the extent to which the QISMC standards are applicable to the new types of entities with which contracts are now authorized.
2. The BBA redefines the respective roles of HCFA and State Medicaid agencies in oversight of Medicaid contractors.
3. The BBA includes provisions to promote coordination of HCFA and State oversight with private accreditation efforts.
4. The BBA establishes specific new requirements for some of the aspects of organization operations addressed by the draft QISMC standards.

HCFA is still in the process of evaluating the BBA requirements. These requirements are substantially in accord with the directions HCFA was already taking under the QISMC process, and nothing in the present draft has been identified as actually conflicting with the provisions of the BBA. Nevertheless, it is likely that some revisions or expansions in the standards and guidelines will be necessary if they are to serve as vehicles for implementing the relevant provisions of the BBA.

HCFA has decided to proceed with release of this draft for public comment pending completion of its analysis of the BBA. The timetable for implementation of the BBA is a short one, and HCFA wishes to assure that States, organizations, and other interested parties have as much opportunity as possible to review the basic concepts and requirements embodied in this document. Reviewers of this draft should assume that

any minor or technical inconsistencies between the standards and guidelines and the BBA will be addressed in the next revision.

President's Advisory Commission

In November 1997, as this draft was nearing completion, the President's Advisory Commission on Consumer Protection and Quality in the Health Care Industry released a Consumer Bill of Rights and Responsibilities (CBRR). The President has instructed the Secretary of Health and Human Services to report by February 1998 on the steps the Department will take to implement the Commission's recommendations. A preliminary review of the CBRR suggests that, to the extent it touches on subject matters addressed in the draft standards, the standards are substantially in accord with the spirit and intent of the related provisions of the CBRR. However, HCFA will need to study the CBRR more thoroughly to determine which of its provisions may be implemented through revisions of the draft standards and guidelines, and which will require changes in Medicare or Medicaid law or regulations.

As in the case of the BBA, HCFA has decided not to delay public review of this draft pending completion of its analysis of the CBRR. Again, reviewers of this draft should assume that minor differences between the standards and the CBRR will be considered in the next revision.

THE ROLE OF THE PURCHASER IN ASSURING QUALITY

The offering of health plan options under Medicare or Medicaid involves a complex interaction among Federal and State agencies, private organizations, and the beneficiaries themselves. The basic transactions and participants may be characterized as follows:

1. A public or private organization decides to offer a health plan, employs or contracts with providers of care, and develops the administrative and information systems necessary to operate the plan.

2. The State, usually through the insurance commissioner or a similar regulatory agency, authorizes the organization to operate the plan. (State licensure is required for Medicare contractors; there is a time-limited exception for certain provider-sponsored organizations. Licensure is also generally required for Medicaid contractors, with exceptions for public organizations, Federally-qualified health centers, and organizations whose solvency is guaranteed by the State or that are not at risk for inpatient and physician services.)

3. HCFA or the State Medicaid agency determines that the organization is qualified to serve Medicare or Medicaid beneficiaries. In making this determination, HCFA or the State may rely in part on assessments of the organization by private accrediting bodies (see the discussion of deeming, below).

4. HCFA or the State Medicaid agency enters into a contract with the organization under which its health plan may be offered to beneficiaries.

5. Individual beneficiaries choose to enroll in (or, in the case of Medicaid, may sometimes be assigned to) an organization in their area that has entered into a Medicare or Medicaid contract.

6. The organization furnishes care and services to its enrollees and continuously monitors its own performance and that of providers in its network.

7. The other entities involved in the licensure, accreditation, and contracting process engage in continuing oversight of the organization's operations. In addition, Medicare quality review and improvement organizations (QIOs) and Medicaid external quality review organizations (EQROs) conduct required external reviews.

Thus there are a large number of actors potentially involved in assessing an organization's operations and performance, including the organization itself, public agencies, various independent bodies, and individual consumers. (This leaves aside the employers, health purchasing groups and coalitions, and other entities that may scrutinize organizations with commercial enrollees, as well as advocacy groups and other third parties.)

A key issue for the QISMC initiative has been to identify the specific role played by HCFA and State Medicaid agencies and the ways in which their functions are distinct from and interrelate with those of other participants in the process. (Note that, in the following discussion, HCFA is considered in its capacity as a purchaser on behalf of Medicare beneficiaries. Of course it also functions as an overseer of State Medicaid purchasing activities.)

HCFA and State Medicaid Agencies as Purchasers

The enrollment of a Medicare or Medicaid beneficiary in an organization actually involves two purchasing decisions. HCFA or the State chooses to contract with the organization, but it is generally the individual beneficiary who decides to enroll under the contract. Medicare beneficiaries choose from among fee-for-service and any managed care plans or other private plans available in their area. Medicaid beneficiaries generally choose between managed care organizations and fee-for-service (with or without a primary care case manager), or between two or more managed care options. (There are limited exceptions to the "two-choice" rule under certain demonstration waivers or when a State requires enrollment in a county-operated organization.)

Theorists of competition in health care might contend that the purchasing decision by the individual beneficiary is the linchpin of the entire system. In this view, informed consumer choice among competing plans is the best way of promoting continuous improvement in quality and efficiency. The role of HCFA and States would be that of neutral scorekeepers, collecting information on organization performance and disseminating the information in formats that would facilitate comparison among organizations on price, benefits, quality, convenience, and other factors important to consumers.

Whatever the theoretical virtues of this model over the long term, the promotion of quality in the current environment requires that HCFA and States take a much more active purchasing role. Although many discussions of comparative plan information have focused on quality and satisfaction, research to date indicates that beneficiaries are chiefly interested in provider choice, then in cost and benefits. Quality issues are of secondary interest, though they might gain in perceived importance if other components, such as benefits, were standardized. Even so, consumers may focus on interpersonal aspects of care rather than technical quality. In addition, despite recent progress in performance measurement, ways have yet to be found of aggregating this information to provide quality comparisons that are both valid and meaningful to consumers.

Thus, while HCFA and States are working actively to improve consumer information, they will retain for the foreseeable future a fundamental responsibility to assure beneficiaries that every organization offered to them meets some basic quality standards. This obligation is owed, not just to beneficiaries, but also to taxpayers. Medicare and Medicaid are government purchasing programs operated for the benefit of defined populations. One of the key responsibilities of HCFA and State Medicaid agencies, as of any government purchasing entity, is to assure that the government gets what it pays for.

Defining quality

In carrying out this responsibility, HCFA and States must necessarily define just what it is they are paying for. For much of their history, Medicare and Medicaid chiefly purchased individual *services*, such as a physician visit or a day of nursing home care. Over time, there was an evolution towards payment for *bundles* of services. Medicaid might pay for total obstetrical care instead of separately for a delivery and for pre- and post-natal visits, while Medicare's prospective payment system pays for total care of an inpatient during a hospital admission, instead of for days of room and board plus tests and other services consumed. Nevertheless, payment was still being made to specific providers for defined items of care furnished to specific individuals. Oversight efforts and program integrity initiatives were largely focused on controlling excessive or unnecessary utilization and on assuring that each service was furnished in accordance with professional standards.

When Medicare and Medicaid make payments to a managed care organization, they are no longer buying care or services at all. The organization receives payment for each enrolled beneficiary whether or not it furnishes any services to that beneficiary. What, then, is the organization selling? One simple answer is that it is selling insurance: it is assuming financial responsibility for health care costs that would otherwise be borne directly by Medicare or Medicaid. If this were so--if organizations were merely performing an intermediary function--it might still be appropriate for quality assurance efforts to focus on the activities of individual providers. However, an organization does not undertake to provide or pay for any service that its enrollees want or that is ordered for them by a physician or other provider. It undertakes to provide what enrollees need. And the only way of ascertaining that the organization has in fact furnished what its enrollees need is to examine outcomes: the effects of care processes on the

health, well being, and satisfaction of individual enrollees or the total enrolled population. Instead of examining individual services, the purchaser must determine whether the sum of the care and services the organization provided achieved its purpose.

For the purpose of QISMC, quality in a managed care organization is defined as the organization's objectively measured performance in protecting and improving the health, functional status, and satisfaction of its enrolled Medicare and Medicaid beneficiaries.

To define quality in this way is to imply that the ultimate purpose of the Medicare and Medicaid programs themselves is to improve the health of the populations they serve. While this basic statement seems unexceptionable, it actually reflects a very different understanding of the role of Medicare and Medicaid from that which prevailed when the two programs were established in 1965. The initial stated intent of the programs was to provide *financial* protection. The original Medicare statute, for example, specified that the hospital insurance program (part A) "provides basic protection against the costs" of hospital and related services (section 1811 of the Social Security Act). Similarly, Medicaid was designed to provide medical assistance for those "whose income and resources are insufficient to meet the costs of necessary medical services" (section 1901).

Of course, the financing or insurance function of the programs remains a critical one, all the more so in light of the dramatic increases in medical costs since their enactment. However, the legislative vision of the role of the programs has steadily broadened. The Medicaid eligibility expansions for pregnant women and children in the late 1980s were explicitly targeted, not just at increasing the number of individuals served, but at reducing infant mortality and promoting the health of children. Medicare coverage, originally restricted to treatment of illness or injury, has been extended to include certain preventive services, with a clear aim of improving health outcomes for beneficiaries. (For example, the addition of new services for diabetics in the BBA is accompanied by a requirement that the Secretary measure outcomes and evaluate "the improvement of the health status" of beneficiaries with diabetes.)

This broadening vision of the purpose of Medicare and Medicaid in turn implies a role for QISMC beyond merely establishing that organizations meet some minimal threshold of performance in order to qualify for a contract. The ultimate goal of QISMC is to improve population health. This means that every organization, whatever its current level of performance, must make continuous efforts to improve that performance. It may be that Plan A merely satisfies the minimum requirements for a contract, while Plan B's performance is far superior. However, because Plan B's performance presumably falls somewhere short of perfection, there will remain room for improvement in outcomes for its enrolled population. Instead of choosing between minimum performance standards and requirements for continuous improvement, QISMC uses both approaches for all participating organizations.

BASIC QUALITY APPROACHES UNDER QISMC

The standards in chapter 2 embody three basic approaches for assuring that organizations with Medicare and Medicaid contracts protect and improve the health and satisfaction of enrolled beneficiaries. The following is a brief discussion of the rationale for and basic principles governing each of the three components; greater detail is found in the interpretive guidelines accompanying each standard.

Performance Measurement and Minimum Performance Standards

Each organization will collect and report data reflecting its performance on standardized measures of health outcomes and enrollee satisfaction, and will meet such minimum performance levels on these measures as may be established under its contract with HCFA or the State Medicaid agency.

As was noted earlier, HCFA and many State Medicaid agencies have already required reporting of standardized data sets. Some States have also negotiated with contractors specific performance targets or required degrees of improvement on particular measures. The standards build on this approach; they do not specify the particular measures for which reporting will be required or the minimum performance levels that organizations will be expected to achieve. These specifications would be developed as part of the process of negotiating a contract with each individual organization.

There are two key reasons for making performance standards a part of the contracting process. First, HCFA and States can focus on measures that are appropriate for a specific organization, reflecting the characteristics and needs of its enrolled population and taking into account its past performance. Second, HCFA and States will have the flexibility needed to respond to new developments in the state of the art of quality measurement.

In adopting minimum performance requirements, it will clearly be important for HCFA and States to assure that the targets are achievable, meaningful, and equitable. Requirements would be established only for measures for which a valid baseline exists--that is, for which there are sufficient data available to allow comparison of the organization's performance with that of other organizations or the fee-for-service sector in serving a similar population. In order to establish these baselines, reporting will be required on more measures than minimum standards will be established for. (This will occur in any event, since reporting serves purposes--such as providing comparative information to consumers--not immediately related to performance improvement.) Other criteria will also guide the selection of measures for which minimum performance levels would be established, including their significance for the health of the organization's enrolled population and the likelihood that they fairly reflect the organization's performance. For example, minimum performance standards would not be established for measures that cannot be readily adjusted to reflect population risk.

The strategy of relying on performance measurement and performance standards to assure and improve quality is heavily dependent on the validity of the data collected and reported by organizations. The standards require that each organization, whatever

the design of its particular information system, assure the completeness and accuracy of all the data it compiles for external reporting or for use in its own quality improvement efforts. However, they do not impose uniform requirements for organizations' data systems; for example, they do not require universal encounter reporting or automated patient records.

Quality Assessment and Performance Improvement

Each organization will operate an internal program of quality assessment and performance improvement that achieves demonstrable improvement in enrollee health, functional status, or satisfaction.

In defining requirements in this area, QISMC seeks a balance between encouraging flexibility and innovation and assuring that every organization conducts meaningful quality improvement activities over a broad spectrum of care or services. The standards specify certain "focus areas" of clinical care and non-clinical services for Medicare and Medicaid enrollees that must be addressed over time by each organization. Examples of focus areas include preventive services for children, care of enrollees with chronic conditions, and mental health and substance abuse services. Within each of these focus areas, the organization is free to select its own particular topics for measurement and improvement.

The expectation is that each organization will conduct quality improvement projects relating to aspects of care and services that are significant for its own population and for which objective and standardized measures of outcomes (or of processes closely correlated with outcomes) exist. The organization will collect baseline data reflecting its performance on one or more measures, implement appropriate interventions to improve its performance, and evaluate the results through follow-up data collection. Each organization will be required to demonstrate at fixed intervals that it has achieved statistically significant improvement in outcomes in each of the required focus areas.

It is recognized that many organizations still have limited experience in conducting well-designed quality improvement projects, and that any given project may take some time to produce measurable improvement. The standards therefore provide for a gradual phase-in of the number of focus areas for which improvement must be demonstrated, allow a single project to be counted as addressing multiple areas, and that improvement over the full spectrum of required focus be shown in multi-year intervals, rather than in any single year.

Structure and Process Requirements

Each organization will demonstrate compliance with specified standards for administrative structures and processes that are closely related to quality of care or beneficiary protection. (Structural measures assess the organization's resources and administrative systems; process measures assess the activities the organization performs on behalf of its enrollees.) Although the focus of QISMC is on measuring and improving outcomes, there are several reasons for including structure and process measures as well.

First, while the main focus of the standards is on improving health, the standards also serve as the mechanism for assuring that organizations provide certain basic consumer protections, for example in addressing enrollee issues or providing adequate information.

Second, HCFA and States must have some basis for assessing new organizations or existing organizations that are seeking their first Medicare or Medicaid contract. For example, there must be assurances that the organization has assessed population needs and structured a network of appropriately qualified providers sufficient to meet those needs, that it has developed systems to assure enrollees' rights, and so on. Whether resources or processes are actually predictive of good quality has been the subject of a long-running debate. At a minimum, it might be said that they are necessary, if not sufficient, for the production of quality care. In the absence of any other way of predicting how a new contractor will perform, structure and process requirements form an important threshold for program participation.

Finally, even in established organizations the scope of performance measures and internal quality improvement efforts is necessarily finite; they cannot touch on every aspect of care and services the organization provides and that is of concern to purchasers or consumers. The organization could improve its performance for large segments of its population but fail to meet the needs of enrollees who require rarely used services or have infrequently encountered problems. Structural measures can help assure that the organization has made and can sustain an acceptable effort to address the needs of all of its enrollees.

The structural measures in the standards are largely based on those used by independent accrediting bodies or State regulators; the burden of meeting them should be minimal for organizations that are already serving commercial populations. Every effort has been made to avoid standards that merely require the organization to produce written operating procedures. The focus is on ascertaining that the organization's systems are actually functioning and achieving their purpose. Whenever possible, the requirements therefore emphasize continuous monitoring by the organization of its own performance and/or feedback into the organization's quality assessment and performance improvement program.

THE QISMC STANDARDS AND GUIDELINES

The standards in chapter 2 and the guidelines in chapter 3 are tools to be used by HCFA and State Medicaid agencies, and potentially by independent reviewers, in ascertaining that organizations assure and continuously improve access and quality of care and protect beneficiaries' rights.

Goals of the Standards

The draft standards are intended to meet several basic objectives.

- Establish uniform standards for Medicare and Medicaid.

The standards are meant to be used both by HCFA in assessing Medicare contractors and by State agencies in assessing Medicaid contractors. There are certain areas in which Medicare or Medicaid law or unique needs of beneficiaries in one program require special standards that are not applicable to the other program; points of divergence are indicated in the standards or guidelines.

- Provide clear guidance to both contractors and reviewers.

Because Medicare and Medicaid reviews can result in official action—granting or denying a government contract—the standards must be applied fairly, objectively, and uniformly. Potential contractors have a right to know exactly what they must do to demonstrate compliance, and inter-reviewer subjectivity must be minimized. Inevitably there will be issues for which assessment of compliance will depend on the circumstances of a specific organization and the expert judgments of individual reviewers. However, the aim throughout has been to translate general concepts into clear expectations, while taking account of the fact that differently structured organizations can achieve objectives in different ways.

- Treat the primary contractor as the responsible entity for all requirements.

All of the standards are written in language that assumes that the organization holding the Medicare or Medicaid contract is itself carrying out each required function or process. Obviously there are many instances in which the prime contractor has subcontracted with other entities to perform some required activities for all enrollees or for specific populations or services. The standards are not intended to restrict organizational structures or (otherwise permissible) contractual arrangements. However, the organization remains wholly accountable to HCFA or the State for compliance with the standards, and it would be inappropriate for the standards to suggest that the locus of responsibility can be shifted to any other entity. Domain 4, on delegation, provides further guidance on the responsibility of the prime contractor for assuring the performance of its subcontractors.

- Apply to all types of services.

The standards are meant to be applicable to all services provided by the organization to Medicare or Medicaid enrollees, including medical care, mental health and substance abuse services, and any additional services (such as dental care) that may be included in a Medicaid contract or furnished to Medicare enrollees as a mandatory or optional supplemental benefit. Thus, for example, the term "practitioner" generally refers to any type of practitioner licensed to practice independently under state law, including physicians, non-physician practitioners furnishing either medical care or mental health and substance abuse treatment, dentists, and other health professionals.

Efforts have been made, in both the standards and the guidelines, to identify instances in which special rules may need to apply for certain services. Other appropriate exceptions or modifications may be identified as the standards are put into effect. However, because these standards are not meant to govern the content of care or professional practice in specific disciplines, the preference has been to maintain a high

level of generality whenever possible. The governing assumption is that an organization should be held to a uniform standard of accountability for all services it contracts to provide, and that the characteristics of processes for assuring availability, accessibility, and quality of care are largely the same regardless of the particular type of care being furnished.

- To the extent feasible, take into account standards used by other agencies or accrediting bodies.

See the discussion of coordination and "deeming," below.

Scope of the Standards

The standards address only areas of organization operations and performance that HCFA has determined to be closely related to quality improvement or to delivery of health care and enrollee services. Obviously, there are other areas of operations that HCFA and States consider in evaluating organizations, such as marketing and enrollment, finances, claims processing, and general administration. Separate regulations, standards, and guidelines exist for each of these areas. The QISMC standards supplement, but do not replace, these other sets of existing standards.

Inevitably there is some overlap between the aspects of performance considered under QISMC and those addressed through other HCFA and State review processes. In order to define the scope of QISMC, some arbitrary distinctions have been necessary. For example, while appropriate access to emergency care clearly has a strong bearing on enrollee health, the organization's responsibilities for paying for emergency care are enforced through reviews of its claims processing system, rather than through QISMC. The standards in section 2.3, describing the information to be furnished to enrollees, cover only information needed by beneficiaries in accessing and evaluating the organization's services. Other key information, such as premium rates and procedures for disenrollment, is covered under separate standards for review of marketing and enrollment materials.

Finally, it should be emphasized that the standards are meant to be used in evaluating the performance of contractors, not of State Medicaid agencies. For example, Medicaid beneficiaries have a right to a fair hearing when an organization denies coverage of a service. It is the State's responsibility, not that of the organization, to assure that beneficiaries have prompt access to the hearing process. Thus the standards in section 2.4, governing resolution of enrollee issues, require only that the organization notify Medicaid beneficiaries of their right to a hearing. Actual enforcement of this right occurs outside the QISMC process.

Organizations Subject to the Standards

The standards and guidelines were originally drafted to apply to HMOs and similar entities–that is, to organizations contracting with Medicare under section 1876 of the Social Security Act and to organizations with similarly comprehensive Medicaid

contracts. The following is a discussion of the extent to which they are applicable to other types of Medicare and Medicaid plans.

Medicare + CHOICE plans. The BBA has broadened the types of health plans that may be offered to Medicare beneficiaries. It establishes three types of Medicare+CHOICE plans: coordinated care plans, MSA plans, and private fee-for-service plans. Coordinated care plans include, not only traditional HMOs, but also point-of-service plans, provider-sponsored organizations, and preferred provider organizations (PPOs); all of these plans use provider networks, with varying degrees of restriction on the use of out-of-network providers. MSA plans, which provide high-deductible coverage to beneficiaries choosing to establish medical savings accounts, may or may not use restrictive provider networks. Private fee-for-service plans do not use networks; they must cover the services of any qualified provider. Although the BBA establishes some quality and consumer protection requirements for all plans, more extensive requirements, especially in the area of quality assurance, are imposed on coordinated care plans and network MSA plans.

In general, it is expected that the standards in this document will apply to any plan with a restrictive network, including all types of coordinated care plans and network MSA plans. The aim is to establish a single standard of quality, regardless of plan structure or model. However, HCFA recognizes that some of the standards may raise specific concerns for certain types of plans, and would welcome comments on this issue.

With respect to non-network plans, some standards (such as those requiring demonstrable improvements in enrollee health) are clearly inapplicable, while others (such as those relating to resolution of enrollee issues) are appropriate for all types of plans. HCFA is analyzing which of the standards should apply to non-network plans and what revisions may be necessary.

Specialized Medicaid plans.

State Medicaid contracts vary widely in the scope of services and populations covered: some cover all acute care; some include long-term care as well; some exclude certain services, such as mental health and substance abuse services; some cover only mental health or substance abuse services; some are targeted to specific populations, such as beneficiaries with HIV disease; and so on.

While the standards should be broadly applicable to any Medicaid contractor, some adjustments may be required when they are used for organizations contracting for a limited scope of services or population. This is clearest in Domain 1, which specifies focus areas for the organization's quality improvement activities. Some of these areas may not be applicable to a particular organization, and the State may wish to substitute other focus areas relevant to the organization's services or target population. However, there are also some individual elements in Domains 2 and 3 that may not apply to every contractor, such as some of the required information to be furnished to enrollees or the standards relating to primary care providers.

Special attention must be paid to cases in which the State itself has divided responsibility for different components of the Medicaid benefit package. For example, some States have "carved out" mental health and substance abuse services from their general managed care contracts and have arranged with distinct organizations to furnish these services. (These purchaser "carve-outs" must be distinguished from situations in which a contracting organization subcontracts with another entity to furnish some benefits; these situations are addressed in Domain 4 of the standards.) In developing its contractual arrangements, the State will need to address the issues of coordination and integration of services and exchange of information among providers. Contracts will need to specify which contracting organization is responsible for which activity, and hold the other organization responsible for cooperation as necessary. In some instances, the State itself may perform certain coordination or information exchange functions. In effect, standards 3.2 (on continuity) and 3.6 (on communication) may be read as applying to the entire system structured by the State, however the State has allocated responsibilities for these functions. The application of the standards to each participating organization would depend the roles it has been given in this overall system.

Finally, the BBA provides for Medicare and, at State option, Medicaid enrollment in Programs of All-Inclusive Care for the Elderly (PACE). These organizations provide comprehensive acute and long-term care through arrangements resembling managed care plans, and are required to engage in quality assurance activities and provide beneficiary protections comparable to those in other managed care plans. However, PACE also present some unique issues, and it will therefore be necessary to develop separate standards for these organizations. This draft should therefore not be read as applying to PACE programs, although the standards will be compatible with and will serve as a model for the PACE standards, to the extent possible.

Use of the Standards

The standards are written in a simple pass/fail format. There is no scoring mechanism, nor any indication that some standards are more important than others. Domain 1, Quality Assessment and Performance Improvement, includes specific phase-in provisions for requirements applicable to an organization's QAPI program. The other domains include no specification of how phase-in might occur.

Obviously, there are organizations now contracting with Medicare or Medicaid that do not currently meet many of the draft standards, and perhaps there is no organization that meets all of them. There are at least two basic approaches HCFA or states could use in applying the standards:

- Establish a scoring system, with a separate score established for each standard or group of standards, and a weighting mechanism to develop an aggregate score. This is the method used, for example, by JCAHO. The minimum aggregate score to qualify for a contract could escalate from year to year. (State Medicaid agencies that use selective contracting for managed care organizations could also use the scoring for this purpose.)

- Establish some form of provisional or probationary status for organizations not meeting the standards. The organization would develop a corrective action plan; progress in implementing the plan would be monitored; and the organization would be expected to reach full compliance by a fixed date.

In addition, because many of the standards assume that the organization is already operational, special methods may be needed for applying the standards in determining contract eligibility for a start-up organization.

These issues are beyond the scope of this document. At this stage, the standards should be read as requirements that HCFA will ultimately expect every Medicare contractor to meet, and the source from which the Medicaid requirements under the BBA will be derived. The rate at which compliance will be expected, and the enforcement mechanisms, will be resolved as the QISMC development process continues.

The Guidelines

The guidelines are chiefly interpretive. That is, they expand on the standards, defining terms, providing a fuller explanation of what does and does not constitute compliance with a given standard, and specifying necessary documentation as appropriate. Again, the aim is to provide the clearest possible guidance to both health plans and reviewers. The decision about what should be a standard and what should be a guideline is necessarily somewhat arbitrary. In general, the principle observed here is that a broad requirement applicable to all contracting organizations should be a standard, while the guidelines indicate acceptable ways of meeting the standard, taking into account permissible variations in organizations' structure and operations. No guideline is supplied when a standard is self-explanatory.

The guidelines do not constitute a reviewer manual. That is, although they specify the information the organization must be able to provide and the criteria to be used by reviewers in assessing that information, they do not detail the mechanics of information-gathering: what is to be furnished in advance, what documents must be available on site, or what questions should be directed to each plan official. The potential information sources are generally self-evident; detailed protocols and training materials will be developed as a routine administrative activity within HCFA and States by personnel with on-site review experience.

COORDINATION AND "DEEMING"

An organization that seeks to serve both Medicare and Medicaid beneficiaries is potentially subject to review by HCFA, the State Medicaid agency, the State licensing authority, a QIO, an EQRO, and one or more independent accrediting bodies. There is considerable potential for overlap in the activities of the different parties engaged in assessing quality in managed care organizations. This may mean duplication of effort on the part of purchasers and regulators, unnecessary administrative burdens on the organizations themselves, and even possible conflict between the standards imposed by different players.

The BBA includes a number of provisions intended to reduce duplicative or conflicting review activities:

- Review of Medicare contractors by peer review organizations (PROs) is replaced with review by quality improvement organizations (QIOs), which could include approved independent accrediting bodies. Under Medicaid, enhanced Federal matching funds will be available for external reviews conducted by entities other than PROs, again including independent accrediting bodies.
- Review activities of QIOs under Medicare are not to duplicate those of approved independent accrediting bodies. A State may apply the same rule for EQRO reviews and may also provide that, in the case of an organization serving both Medicare and Medicaid enrollees, EQRO activities will not duplicate those of the QIO.
- An independently accredited Medicare managed care organization is deemed to have met requirements related to internal quality assurance and confidentiality if the accrediting body is approved by the Secretary and uses standards at least as stringent as Medicare's.
- A Medicare contractor may be exempted from QIO review if it has an "excellent record" in quality assurance and other areas.
- Although most Medicare contractors are required to be licensed by the State, States are preempted from enforcing, with respect to Medicare enrollees, certain standards "inconsistent" with Medicare's.

HCFA is still in the process of formulating the rules it will follow in implementing these complex provisions. For the purpose of considering the standards set forth in chapter 2, perhaps the key point to note is that, while the BBA permits and sometimes requires HCFA and States to rely on reviews by outside entities, this is true only to the extent that the outside reviewers use standards consistent with those established under Medicare and Medicaid. HCFA and States thus retain the ultimate responsibility to determine what constitutes acceptable quality for Medicare and Medicaid enrollees.

Even before enactment of the BBA, one of the goals of the QISMC initiative was to promote greater uniformity in the standards used by Medicare and Medicaid and, to the extent feasible, State regulators, private purchasers, and accrediting bodies. The original draft of the standards contained in chapter 2 was developed in early 1997 after careful comparison with the following sets of standards developed by outside entities: draft 1997 National Committee on Quality Assurance (NCQA) accreditation standards for managed care organizations and draft accreditation standards for managed behavioral healthcare organizations; Joint Commission on Accreditation of Healthcare Organizations (JCAHO) accreditation standards for health care networks; National Association of Insurance Commissioners model acts on managed care plan network adequacy, quality assessment and improvement, and utilization review; and URAC network accreditation standards.

In Domains 2, 3, and 4 of this draft, many concepts, and sometimes specific phrases, were adopted from these other sets of standards. However, the draft rarely conforms very closely to any one of these other sets, for several reasons. First, as noted earlier, one aim was to provide clearer guidance to organizations and reviewers; standards and guidelines in use by private accrediting bodies may provide considerably more latitude to individual reviewers. Second, the standards in use by private bodies were generally developed for organizations serving employer groups, and did not always address the special needs of Medicare and Medicaid beneficiaries. Finally, of course, there was wide variance in the outside standards themselves. The draft could have been made to conform to the standards of any one outside body, but not all of them.

HCFA does not believe that the minor differences in these domains between its standards and those of independent accrediting bodies will present a significant barrier to coordination and deeming. For subject areas common to HCFA and other standards, the actual review protocols of independent bodies are not likely to require major modification. Commonly, the accrediting body might need to add one or two questions to interviews or request some additional documentation, rather than revise its entire procedure.

Domain 1, on the other hand, is significantly different from requirements imposed under other sets of standards, and independent bodies will need to make substantial changes in their review methods for deeming to be possible. It is HCFA's express intention to be a leader in the area of quality improvement for managed care. Medicare and Medicaid are the major purchasers of managed care services, and HCFA's decisions on this subject are therefore likely to have an important impact on how organizations shape their quality measurement and improvement systems, as well as on the expectations imposed on organizations by other purchasers. For this reason, it would have been inappropriate for HCFA to seek to arrive at the lowest common denominator in this critical area. HCFA hopes that the innovative approaches represented in Domain 1 will serve as a model for other purchasers and regulators.

1 **Quality Assessment and Performance Improvement**

1.1 Basic Requirements. The organization:

1.1.1 Achieves required minimum levels of performance, as established by the Medicare program or the State Medicaid agency, on standardized quality measures; and

1.1.2 Conducts a quality assessment and performance improvement (QAPI) program that achieves, through ongoing measurement and intervention, demonstrable and sustained improvement in significant aspects of clinical care and non-clinical services that can be expected to affect enrollee health status, functional status, and satisfaction.

1.2 Minimum Performance Levels.

1.2.1 The organization measures its performance, using standard measures established or adopted by the Medicare program or the State Medicaid agency, and reports its performance to the applicable agency.

1.2.2 The organization achieves any minimum performance levels on specific measures that may be established by the Medicare program or the State Medicaid agency.

1.2.3 The organization meets any goals for performance improvement on specific measures that may be established by the Medicare program or the State Medicaid agency.

1.3 Scope of QAPI Activities. Projects conducted under the organization's QAPI program address and achieve improvement in major focus areas of clinical care and non-clinical services.

1.3.1 Definitions

1.3.1.1 A project is an initiative by the organization to measure its own performance in one or more focus areas, undertake system interventions to improve its performance, and monitor the effect of those interventions.

1.3.1.2 A project will be considered to have achieved demonstrable improvement in a focus area during any review year in which an improvement meeting the minimum thresholds of standard 1.4.4 is measured.

1.3.1.3 For the purpose of standard 1.3.2.1, the first review year is, in the case of an organization with a Medicare or Medicaid contract in effect on the date these standards are put into effect by HCFA or the State Medicaid agency, the year beginning on that date. For an organization that first enters into a Medicare or Medicaid contract after the date these standards are adopted by HCFA or the State Medicaid agency, the first review year is the year beginning on the effective date of that contract.

1.3.2 **Phase-In and Scope.** An organization meets the requirements of this section if—

1.3.2.1 By the end of the first review year, the organization has initiated a project or projects addressing any two of the clinical focus areas specified under standard 1.3.3 (in the case of an organization with Medicare enrollees) or 1.3.4 (in the case of an organization with Medicaid enrollees) and any two of the non-clinical areas specified under standard 1.3.5.

1.3.2.2 By the end of the second review year, the organization has achieved demonstrable improvement in two clinical focus areas and in two non-clinical areas.

1.3.2.3 During the third review year, the organization achieves demonstrable improvement in three clinical focus areas and two non-clinical areas.

1.3.2.4 During the fourth review year, the organization achieves demonstrable improvement in four clinical focus areas and two non-clinical areas.

1.3.2.5 By the end of each review year after the fourth review year—

1.3.2.5.1 the organization has, during the preceding three years, achieved demonstrable improvement in each of the non-clinical focus areas specified under standard 1.3.5;

1.3.2.5.2 an organization with Medicare members has, during the preceding two years, achieved demonstrable improvement in each of the clinical focus areas specified under standard 1.3.3;

1.3.2.5.3 an organization with Medicaid members has, during the preceding three years, achieved demonstrable improvement in each of the clinical focus areas specified under standard 1.3.4.

1.3.2.6 In each review year, an organization with both Medicare and Medicaid members must meet the requirements for an organization with Medicare members and the requirements for an organization with Medicaid members.

1.3.3 **Medicare clinical focus areas.** Clinical focus areas applicable to Medicare enrollees are as follows:

1.3.3.1 Prevention for Medicare enrollees;

1.3.3.2 Chronic diseases affecting Medicare enrollees;

1.3.3.3 Care of Medicare enrollees receiving hospital inpatient or ambulatory surgery services, including post-discharge care;

1.3.3.4 Care of Medicare enrollees residing in long-term care facilities;

1.3.3.5 Care of Medicare enrollees who are unusually dependent on others or on devices but who do not reside in long-term care facilities;
1.3.3.6 Mental health treatment for Medicare enrollees; and
1.3.3.7 Substance abuse treatment for Medicare enrollees.

1.3.4 Medicaid clinical focus areas. Clinical focus areas applicable to Medicaid enrollees are as follows:
1.3.4.1 Prevention for adult Medicaid enrollees;
1.3.4.2 Prenatal care for pregnant Medicaid enrollees;
1.3.4.3 Well-child care for Medicaid enrollees who are children or adolescents;
1.3.4.4 Ambulatory care for Medicaid enrollees who are enrolled under family or child categories;
1.3.4.5 Chronic diseases affecting elderly or disabled Medicaid enrollees;
1.3.4.6 Care of Medicaid enrollees receiving hospital inpatient or ambulatory surgery services, including post-discharge care;
1.3.4.7 Care of Medicaid enrollees residing in long-term care facilities;
1.3.4.8 Care of Medicaid enrollees who are unusually dependent on others or on devices but who do not reside in long-term care facilities;
1.3.4.9 Mental health treatment for Medicaid enrollees;
1.3.4.10 Substance abuse treatment for Medicaid enrollees; and
1.3.4.11 Care of Medicaid enrollees who are developmentally disabled.

1.3.5 Non-clinical focus areas. Non-clinical focus areas applicable to both Medicare and Medicaid enrollees are as follows:
1.3.5.1 Complaints and grievances;
1.3.5.2 Denials of authorization or payment for services;
1.3.5.3 Cultural competence;
1.3.5.4 Availability of desired services;
1.3.5.5 Convenience of available services; and
1.3.5.6 Timeliness of available services.

1.3.6 Multiple focus areas. A single project may be considered as addressing more than one required focus area, or as addressing services for both Medicare and Medicaid enrollees, so long as the project meets the requirements of standard 1.4 for each focus area and/or population addressed.

1.3.7 Special projects.
1.3.7.1 Alternative focus areas. An organization may propose alternative focus areas to HCFA or to the State Medicaid agency, or HCFA or the State agency may designate alternative focus areas for any organization or multiple organizations.
1.3.7.2 Collaborative projects. Organizations may satisfy the requirements of standard 1.3.2 by participating in

collaborative projects, subject to the approval of HCFA or the State Medicaid agency.

1.3.8 **Multi-year projects.** If a project is conducted over a period of more than one review year—

1.3.8.1 The project will be considered as achieving improvement in each year for which it achieves an improvement meeting the requirements specified in standard 1.4.4;

1.3.8.2 A project may be considered as achieving improvement in each year for which it achieves an improvement that does not meet the requirements specified in standard 1.4.4, but that constitutes an intermediate target specified in a project work plan developed in consultation with HCFA or the State Medicaid agency.

1.4 Assessment of QAPI Projects

1.4.1 **Selection of topics.** Within each required focus area, the organization selects a specific topic or topics to be addressed by a project.

1.4.1.1 Topics are identified through continuous data collection and analysis by the organization that reflects all aspects of patient care and member services.

1.4.1.2 Topics are systematically selected and prioritized to achieve the greatest practical benefit for enrollees.

1.4.1.3 Selection of topics takes into account: the prevalence of a condition among, or need for a specific service by, the organization's enrollees; enrollee demographic characteristics and health risks; and the interest of consumers in the aspect of care or services to be addressed.

1.4.1.4 The QAPI program provides opportunities for enrollees to participate in the selection of project topics and the formulation of project goals.

1.4.2 **Quality indicators.** Assessment of the organization's performance for each selected topic is measured using one or more quality indicators.

1.4.2.1 Quality indicators are objective, clearly and unambiguously defined, and based on current clinical knowledge; when generally accepted indicators are applicable to the topic, use of those measures is preferred.

1.4.2.2 All indicators measure outcomes: that is, changes in health status, functional status, and/or satisfaction. Measures of processes are used as a proxy for outcomes only when those processes have been established through published studies or a consensus of relevant practitioners to be significantly related to outcomes.

1.4.2.3 Indicators selected for a topic in a clinical focus area (under standard 1.3.3 or 1.3.4) include at least some measure of change in health status or functional status and may also include measures of satisfaction.

1.4.2.4 The organization selects some indicators for which data are available that allow comparison of the organization's performance to that of similar organizations or to local, state, or national benchmarks.

1.4.3 Data collection and methodology. Assessment of the organization's performance on the selected indicators is based on systematic, ongoing collection and analysis of valid and reliable data.

1.4.3.1 The organization establishes a baseline measure of its performance on each indicator, measures changes in performance, and continues measurement for at least one year after a desired level of performance is achieved.

1.4.3.2 Sampling methodology for assessment of the organization's performance shall be such as to assure that the data collected reliably reflect the performance of all practitioners and providers who serve Medicare or Medicaid enrollees and whose activities are the subject of the indicator.

1.4.4 Demonstrable and sustained improvement. The organization's interventions result in improvement in the selected quality indicator(s) that is significant and sustained over time.

1.4.4.1 The organization (a) achieves a benchmark level of performance that is defined in advance by the organization (or by HCFA or the State Medicaid agency), or (b) achieves a reduction of at least 10 percent in the number of enrollees who do not achieve the outcome defined by the indicator (or, if applicable, in the number of instances in which the desired outcome is not achieved).

1.4.4.2 The improvement is reasonably attributable to interventions undertaken by the organization.

1.4.4.3 The organization demonstrates through continued measurement that its performance is sustained for at least one year at the minimum level required under standard 1.4.4.1.

1.4.4.4 If data collection is conducted for a random sample of the population, baseline and follow-up sampling shall be conducted using the same methodology, and shall demonstrate that an improvement measured under standard 1.4.4.1 is statistically significant with a p value of less than 0.05.

1.5 Performance Measurement. The organization maintains a health information system that collects, analyzes, integrates, and reports data

necessary to measure its performance and to develop and implement its QAPI program.

1.5.1 The system collects data on enrollee and provider characteristics, and on services furnished to enrollees, as needed to guide the selection of QAPI project topics (standard 1.4.1) and to meet the data collection requirements for QAPI projects (standard 1.4.3).

1.5.2 The organization assures that information received from providers is reliable and complete.

1.5.2.1 The organization verifies the accuracy and timeliness of reported data.

1.5.2.2 Data are screened for completeness, logic, and consistency.

1.5.2.3 Service information is collected in standardized formats to the extent feasible and appropriate.

1.6 Interim Standards for New Contractors. An organization that first enters into a Medicare or Medicaid contract after the date these standards are adopted by HCFA or the State Medicaid agency has a documented and well-designed strategy for achieving compliance with standards 1.3 through 1.5 and demonstrates a commitment to implementing the strategy.

1.6.1 The organization develops and implements an annual work plan, approved by HCFA or the State Medicaid agency, that—

1.6.1.1 Details specific activities to achieve compliance with each of the component standards of standard 1.3 through 1.5;

1.6.1.2 Specifies time frames and identifies responsible parties for each activity.

1.6.2 The organization has a process for formal evaluation, at a minimum annually, of the impact and effectiveness of the QAPI program strategy, and for making necessary changes.

1.6.3 The organization's QAPI program is administered through clear and appropriate administrative arrangements, such that:

1.6.3.1 The policymaking body oversees and is accountable for the QAPI program.

1.6.3.2 A designated senior official is responsible for QAPI implementation.

1.6.3.3 Employed or affiliated providers and consumers actively participate in the QAPI program.

1.6.3.4 There is collaboration among all aspects of the QAPI activity and other functional areas of the organization impacting the quality of clinical care and service delivery.

2 Enrollee Rights

2.1 Policies on Enrollee Rights.

2.1.1 The organization implements written policies with respect to the enrollee rights specified in standard 2.2.

2.1.1.1 Policies are communicated to enrollees, in the enrollee statement furnished in accordance with standard 2.3, and to the organization's staff and affiliated providers, at the time of initial employment or affiliation and annually thereafter.

2.1.1.2 The organization monitors and promotes compliance with the policies by the organization's staff and affiliated providers.

2.1.2 The organization assures that services are accessible to all enrollees, including those with limited English proficiency or reading skills, with diverse cultural and ethnic backgrounds, and with physical and mental disabilities.

2.1.3 The organization assures compliance with Federal and State laws affecting the rights of enrollees.

2.2 Enrollee Rights. Each enrollee has a right–

2.2.1 to be treated with respect, dignity, and consideration for enrollee privacy;

2.2.1.1 The organization implements procedures to assure the confidentiality of health and medical records and of other information about enrollees.

2.2.1.2 The right to privacy includes the right to approve or refuse the release of identifiable personal information by the organization, except when such release is required by law.

2.2.1.3 The organization implements specific policies with respect to confidentiality and privacy for minors, subject to applicable law.

2.2.2 to choose providers from among those affiliated with the organization;

2.2.2.1 Each enrollee may select his or her primary care provider from among those accepting new Medicare or Medicaid enrollees.

2.2.2.2 Each enrollee may refuse care from specific practitioners or providers.

2.2.3 to participate in decision-making regarding his or her health care;

2.2.3.1 The organization provides for the enrollee's representative to facilitate care or treatment decisions when the enrollee is unable to do so.

2.2.3.2 The organization provides for enrollee or representative involvement in decisions to withhold resuscitative services, or to forgo or withdraw life-sustaining treatment, and complies with requirements of Federal and State law with respect to advance directives.

2.2.4 to receive information on available treatment options or alternative courses of care;

2.2.5 to have access to his or her medical records in accordance with applicable Federal and State laws; and

2.2.6 to obtain a prompt resolution, through the procedures established under standard 2.4, of issues raised by the enrollee, including complaints or grievances and issues relating to authorization, coverage, or payment of services.

2.3 Enrollee Information

2.3.1 Each enrollee receives, at the time of enrollment and at least annually thereafter, a written statement including information on:

2.3.1.1 Enrollee rights;

2.3.1.2 Enrollee responsibilities, including the responsibility to provide information needed for treatment, to follow the organization's procedures for obtaining services, and to follow instructions and guidelines given by those providing services;

2.3.1.3 The names and locations of network providers, including information on which providers are accepting new Medicare or Medicaid patients and any restrictions on enrollees' ability to select from among network providers;

2.3.1.4 Benefits and services included and excluded as a condition of enrollment, including a description of how the organization evaluates new technology for inclusion as a covered benefit;

2.3.1.5 Procedures for obtaining services, including authorization requirements, any special procedures for obtaining mental health and substance abuse services, procedures for obtaining out-of-area coverage and, in the case of enrollees eligible for a point-of-service benefit, procedures for obtaining services through the benefit, including special conditions or charges that may apply;

2.3.1.6 In the case of Medicaid enrollees, procedures for obtaining services covered under the Medicaid state plan and not covered by the organization, and notice of the right to obtain family planning services from any Medicaid-participating provider (unless otherwise restricted);

2.3.1.7 Provisions for after-hours and emergency coverage, including the organization's policy on when enrollees should seek direct access to emergency care;

2.3.1.8 Policies on referrals for specialty care and other services not furnished by the enrollee's primary care provider;

2.3.1.9 Charges to enrollees, if applicable;

2.3.1.10 Procedures established under standard 2.4 for resolving enrollee issues, including complaints or grievances and

issues relating to authorization of, coverage of, or payment for services;

2.3.1.11 Procedures for changing primary care providers;

2.3.1.12 Procedures for recommending changes in policies or services; and

2.3.1.13 Notice of the right to obtain information on physician incentive plans and results of required surveys.

2.3.2 The organization notifies enrollees affected by termination of or changes in benefits, services, service sites, or affiliated providers.

2.3.3 Enrollee information is--

2.3.3.1 readable and easily understood;

2.3.3.2 available in the language(s) of the major population groups served and, as needed, in alternative formats for the visually impaired.

2.3.4 The organization assesses and improves the effectiveness of its communications with enrollees through consumer testing, surveys, or other means.

2.4 Resolution of Enrollee Issues. The organization has a system for resolving issues raised by enrollees, including complaints or grievances; issues relating to authorization of, coverage of, or payment for services; and, in the case of Medicare enrollees, issues relating to discontinuation of a service. [NOTE: references to an enrollee in these standards include reference to an enrollee's representative.]

2.4.1 Intake of Enrollee Issues. The organization follows written procedures for the receipt and initial processing of all issues raised by enrollees. The organization--

2.4.1.1 documents each issue raised by an enrollee;

2.4.1.2 promptly determines whether the issue is to be resolved through: (a) the grievance process established under standard 2.4.2, (b) the process for making initial determinations on coverage and payment issues established under standard 3.3, or (c) the process for resolution of disputed initial determinations established under standard 2.4.3;

2.4.1.3 acknowledges receipt of the issue and explains to the enrollee the process to be followed in resolving his or her issue;

2.4.1.4 assists the enrollee as needed in completing forms or taking other necessary steps to obtain resolution of the issue; and

2.4.1.5 informs the enrollee of any applicable mechanism for resolving the issue external to the organization's own processes.

2.4.2 Grievances. The organization implements a procedure, with clearly explained steps and time limits for each step, for the resolution of a complaint or grievance.

2.4.2.1 The grievance is transmitted in a timely manner to staff who have authority to take corrective action. A

grievance relating to quality of care is transmitted to appropriately qualified clinical personnel.

2.4.2.2 The organization investigates the grievance and notifies the concerned parties of the results of the investigation and the proposed resolution.

2.4.2.3 The organization provides an opportunity for reconsideration of the proposed resolution.

2.4.2.4 The organization tracks each grievance until its final resolution.

2.4.2.5 The organization has an expedited grievance process for issues requiring immediate resolution.

2.4.3 Reconsideration of Coverage and Payment Determinations. The organization implements a procedure, with clearly explained steps and time limits for each step, for reviewing requests for reconsideration of initial decisions not to provide or pay for a service.

2.4.3.1 The organization's notice to an enrollee and/or provider of its decision to deny, limit, or discontinue authorization of, or payment for, a service includes information required under standard 3.3.1.5, including information about how to obtain a reconsideration of the decision. The notice to the enrollee must be in writing.

2.4.3.2 The organization's process complies with procedural requirements and time limits established by HCFA or the State Medicaid agency;

2.4.3.3 Requests for reconsideration by the organization of a denial based on lack of medical necessity are reviewed by an individual with appropriate clinical expertise who is not the individual who made the initial determination.

2.4.4 Monitoring of Issue Resolution Processes. The organization maintains, aggregates and analyzes information on the nature of issues raised by enrollees and on their resolution.

2.4.4.1 The information is used to develop activities under the organization's QAPI program, both to improve the issue resolution process itself and to make improvements that address other system issues raised in the process.

2.4.4.2 Information related to coverage and payment issues is maintained for at least three years following final resolution of the issue, and is made available to the enrollee on request.

3 **Health Services Management**

3.1 **Availability and Accessibility.** The organization assures that all covered services, including additional or supplemental services contracted for by or on behalf of Medicare or Medicaid enrollees are available and accessible.

3.1.1 The organization maintains and monitors a network of providers, supported by written arrangements, that is sufficient to provide timely access to covered services.

3.1.1.1 A new contractor, or an established contractor seeking an expansion of its service area, demonstrates that the numbers and types of providers available to enrollees are sufficient to meet anticipated needs of the population and area to be served.

3.1.1.2 An established contractor establishes standards for timeliness of access to care and member services that meet or exceed such standards as may be established by HCFA or the State Medicaid agency, continuously monitors the extent to which it meets these standards, and takes corrective action as necessary.

3.1.2 All providers are determined to be qualified through the process established under standard 3.5.

3.1.3 When medically necessary, the organization makes services available 24 hours a day, 7 days a week.

3.2 **Continuity of Care.** The organization promotes continuity of care and integration of services through:

3.2.1 Use of a health care professional who is formally designated as having primary responsibility for coordinating the enrollee's overall health care;

3.2.1.1 The organization's policies specify whether services are coordinated by the enrollee's primary care provider or through some other means;

3.2.1.2 Regardless of the mechanism adopted for coordination of services, the organization assures that each enrollee has an ongoing source of primary care.

3.2.2 Programs for coordination of care, including:

3.2.2.1 Identification of enrollees with complex needs and development of services and programs to assist them in meeting those needs;

3.2.2.2 Coordination of medical care, mental health services and substance abuse services, and social services and community resources;

3.2.3 Procedures for timely communication of clinical information among providers, as specified in standard 3.6;

3.2.4 Measures to assure that enrollees are informed of specific health care needs that require follow-up and receive, as appropriate, training in self-care and other measures enrollees may take to promote their own health; and

3.2.5 Systems to address barriers to enrollee compliance with prescribed treatments or regimens.

3.3 Service Authorization

3.3.1 The organization follows written policies and procedures, reflecting current standards of medical practice, for processing requests for initial authorization of services or requests for continuation of services.

3.3.1.1 The policies specify time frames for responding to requests for initial and continued determinations, specify information required for authorization decisions, provide for consultation with the requesting provider when appropriate, and provide for expedited response to requests for authorization of urgently needed services.

3.3.1.2 Criteria for decisions on coverage and medical necessity are clearly documented, are based on reasonable medical evidence or a consensus of relevant practitioners, and are regularly updated.

3.3.1.3 Mechanisms are in place to ensure consistent application of review criteria and compatible decisions.

3.3.1.4 A clinical peer reviews all decisions to deny authorization on grounds of medical appropriateness.

3.3.1.5 The requesting provider and the enrollee are promptly notified of any decision to deny, limit, or discontinue authorization of services. The notice specifies the criteria used in denying or limiting authorization and includes information on how to request reconsideration of the decision pursuant to the procedures established under standard 2.4.3. The notice to the enrollee must be in writing.

3.3.1.6 Compensation to persons or organizations conducting utilization management activities is not based, directly or indirectly, on the quantity or type of adverse determinations rendered.

3.3.1.7 The organization does not prohibit providers from advocating on behalf of enrollees within the utilization management process.

3.3.2 All requests for authorization are recorded, along with their disposition, and aggregate data is compiled for use in QAPI.

3.3.3 The organization furnishes information to all affiliated providers about enrollee benefits and utilization management policies.

3.4 Practice Guidelines and New Technology

3.4.1 The organization adopts and disseminates practice guidelines or criteria for the provision of specific services.

3.4.1.1 Guidelines are based on reasonable medical evidence or a consensus of relevant practitioners, are developed in consultation with affiliated providers, and are reviewed and updated periodically.

3.4.1.2 Guidelines are communicated to providers and, as appropriate, to enrollees.

3.4.1.3 Decision making in utilization management, enrollee education, interpretation of covered benefits, and other areas to which the guidelines are applicable is consistent with the guidelines.

3.4.2 The organization implements written policies and procedures for evaluating new medical technologies and new uses of existing technologies.

3.4.2.1 The evaluations take into account coverage decisions by Medicare intermediaries and carriers, national Medicare coverage decisions, and federal and state Medicaid coverage decisions, as appropriate.

3.5 Provider Qualification and Selection. The organization implements a documented process for selection and retention of affiliated providers.

3.5.1 For each physician or other individual practitioner, including each practitioner within a contracting group who provides services to the organization's enrollees, the process includes:

3.5.1.1 Procedures for initial credentialing, including a written application, verification of licensure and other information from primary sources, and site visits as appropriate.

3.5.1.2 Procedures for recredentialing, at least every two years, through a process that updates information obtained in initial credentialing and considers performance indicators collected through the QAPI program, the utilization management system, the grievance system, enrollee satisfaction surveys, and other activities of the organization.

3.5.1.3 A process for receiving advice from affiliated practitioners with respect to criteria for credentialing and recredentialing of individual practitioners.

3.5.1.4 Written policies and procedures for suspending or terminating affiliation with a contracting physician, including an appeals process.

3.5.1.5 Formal selection and retention criteria that do not discriminate against practitioners who serve high-risk populations or who specialize in the treatment of costly conditions.

3.5.2 For each institutional provider or supplier, the organization determines, and redetermines at specified intervals, that the provider or supplier–

3.5.2.1 Is licensed to operate in the State, and in compliance with any other applicable State or Federal requirements;

3.5.2.2 Is certified as meeting the requirements of Medicare or Medicaid (as applicable); is reviewed and approved by an approved accrediting body; or is determined by the

organization to meet standards established by the organization itself; and

3.5.2.3 In the case of a provider or supplier providing services to Medicare enrollees, is approved for participation in Medicare. (Note: This requirement does not apply to providers of additional or supplemental services for which Medicare has no approval standards.)

3.5.3 The organization notifies licensing or disciplinary bodies or other appropriate authorities when a practitioner's or provider's affiliation is suspended or terminated because of quality deficiencies.

3.6 Enrollee Health Records and Communication of Clinical Information. The organization implements appropriate standards to assure that the organization and its providers have the information required for effective and continuous patient care and for quality review, and conducts an ongoing program to monitor compliance with those standards.

3.6.1 The organization assures that each provider furnishing services to enrollees maintains an enrollee health record in accordance with standards established by the organization, taking into account professional standards.

3.6.1.1 The organization enforces standards for health record content and organization, including specifications of basic information to be included in each health record.

3.6.1.2 The organization implements a process to assess and improve the content, legibility, organization, and completeness of enrollee health records.

3.6.1.3 Enrollee health records are available and accessible to the organization and to appropriate state and federal authorities, or their delegates, involved in assessing the quality of care or investigating enrollee grievances or complaints.

3.6.2 The organization assures appropriate exchange of information among providers, such that:

3.6.2.1 A provider making a referral transmits necessary information to the provider receiving the referral;

3.6.2.2 A provider furnishing a referral service reports appropriate information to the referring provider;

3.6.2.3 Providers request information from other treating providers as necessary to provide care; and

3.6.2.4 If the organization offers a point-of-service benefit or other benefit providing coverage of services of non-network providers, the organization transmits information about services used by an enrollee under the benefit to the enrollee's primary care provider.

4 Delegation. The organization oversees and is accountable for any functions or responsibilities that are described in these standards and that are delegated to any contractor.

4.1 The following basic requirements apply to all delegated functions:

4.1.1 A written agreement specifies the delegated activities and reporting responsibilities of the contractor and provides for revocation of the delegation or other remedies for inadequate performance.

4.1.2 The organization evaluates the contractor's ability to perform the delegated activities prior to delegation.

4.1.3 The performance of the contractor is monitored on an ongoing basis and formally reviewed by the organization at least annually.

4.2 The following restrictions apply to delegation of certain functions:

4.2.1 An organization with Medicare enrollees may fully delegate the authorization functions described in standard 3.3 to a contractor, but may not fully delegate the reconsideration process described in standard 2.4.3, and may not delegate any part of this process to a contractor that is unable to comply with standard 2.4.3.3.

4.2.2 If the organization delegates selection of practitioners or providers to another entity, the organization retains the right to approve, suspend, or terminate any individual practitioner, site, or provider selected by that entity.

CHAPTER 3: GUIDELINES

1. Quality Assessment and Performance Improvement

(Note: standards appear in **bold face.**)

1.1. Basic Requirements. The organization:

1.1.1. Achieves required minimum levels of performance, as established by the Medicare program or the State Medicaid agency, on standardized quality measures; and

1.1.2. Conducts a quality assessment and performance improvement (QAPI) program that achieves, through ongoing measurement and intervention, demonstrable and sustained improvement in significant aspects of clinical care and non-clinical services that can be expected to affect enrollee health status, functional status, and satisfaction.

The basic standard for this domain establishes two distinct, but necessarily related, strategies for promoting quality of care in organizations serving Medicare or Medicaid enrollees.

First, the Medicare program or the State Medicaid agency will establish minimum requirements for specified aspects of care, using objective and standardized measures of organization performance. For example, a State agency might require all organizations with Medicaid enrollees to achieve 90 percent immunization rates for Medicaid children.

Second, the organization must operate its own internal QAPI program that is outcome-oriented and that achieves demonstrable and sustained improvement in care and services. In general, the individual standards in this domain assume that an organization will continuously monitor its own performance on a variety of dimensions of care and services for enrollees, identify its own areas for potential improvement, and carry out individual QAPI projects which undertake system interventions and monitor the effect of those interventions.

The degree to which these two quality improvement strategies overlap will vary depending on an individual organization's performance. In the example given, some contracting organizations may already meet the 90 percent immunization requirement, while others may need to undertake improvement efforts to come into compliance. An organization already in compliance with the State's standard would not be required to focus its QAPI efforts on improving this aspect of care. It might choose on its own to undertake a QAPI project to achieve some even higher standard, or it might choose to focus on some other aspect of care. On the other hand, an organization that did not meet the State's immunization standard would presumably wish to target its QAPI activities in order to come into compliance. Thus, while there is clearly an interplay between minimum performance requirements and the QAPI requirements in this section, the two are not synonymous. An organization that meets all specified performance thresholds would still be required to operate an effective QAPI program as defined in this domain.

The remaining standards in this domain constitute elaborations of the basic requirement set forth in standard 1.1. They are as follows:

- Standard 1.2, Minimum Performance Levels, specifies that organizations must report their performance on standardized measures and achieve established performance levels for specified measures or performance improvement goals for those measures.

- Standard 1.3, Scope of QAPI Activities, requires that an organization's individual improvement projects, in the aggregate, address a broad spectrum of key aspects of enrollee care and services. It also includes specifications for phase-in of these requirements for new and current Medicare and Medicaid contractors.

- Standard 1.4, Assessment of QAPI Projects, establishes the criteria for assessment of each individual QAPI project carried out by the organization.

- Standard 1.5, Performance Measurement, assesses the extent to which an organization's information systems support its QAPI program.

- Standard 1.6 , QAPI Program Strategy, is applicable only to newly contracting organizations. It specifies basic structure and process requirements for the organization's QAPI program, requires that the organization have a strategy for achieving compliance with standards 1.3 through 1.5, and assesses the adequacy of the resources devoted to that effort.

The transitional structure and process requirements established under standard 1.6 are to be distinguished from the phase-in provisions established under standard 1.3. Any organization newly applying for a Medicare or Medicaid contract must meet the structural requirements of standard 1.6 before the contract will take effect. After the first full year of contracting, Medicare or Medicaid review of the organization will ordinarily focus on whether the organization is meeting the phase-in schedule for initiating specified numbers of QAPI projects and achieving improvement through these projects.

If the organization meets the timetable for a phased broadening of the scope of its QAPI activities, it will no longer be reviewed under standard 1.6 after the first contracting year. An organization would continue to be subject to standard 1.6 if, for example, it failed to meet the standard 1.3 timetable, or if its individual projects failed to meet the criteria of standard 1.4.

A newly contracting organization may elect to be assessed under standard 1.6 for a minimum of two years from the initial effective date of the organization's contract with Medicare or Medicaid; after that period it must ordinarily meet the requirements of standard 1.3. However, the Medicare program or the State Medicaid agency may allow a new contractor that is not in compliance with standard 1.3 to continue to be assessed under standard 1.6 for a longer period. The duration of this period would be established at the sole discretion of the Medicare program or the State agency, taking

into account the nature of the organization's deficiencies and its progress in correcting them.

1.2. Minimum Performance Levels.

1.2.1. The organization measures its performance, using standard measures established or adopted by the Medicare program or the State Medicaid agency, and reports its performance to the applicable agency.

1.2.2. The organization achieves any minimum performance levels on specific measures that may be established by the Medicare program or the State Medicaid agency.

1.2.3. The organization meets any goals for performance improvement on specific measures that may be established by the Medicare program or the State Medicaid agency.

Measurement and reporting requirements, and minimum performance levels or improvement goals, will not be detailed in these standards. Instead, requirements will be established as a part of the annual process of negotiating the Medicare or Medicaid contract with each organization. Some requirements may apply to all Medicare or Medicaid contractors. Others may apply to a specific contractor, reflecting the organization's past performance in a particular aspect of care or unique characteristics of the organization's enrolled population. (See the introduction for a discussion of how performance measures would be selected and minimum performance thresholds established.)

Note that, in addition to imposing minimum performance thresholds, the Medicare program or a State Medicaid agency may identify a particular aspect of care or services and require a contracting organization to achieve a specified degree of improvement in that area, rather than meet a uniform performance threshold. Such a requirement might, for example, be imposed on a single organization that is an outlier on a specific performance measure. The organization would be required to address that area through a QAPI project until a desired level of improvement was achieved. Or a State Medicaid agency might determine that all organizations in a given region needed to focus on a specific aspect of care, either individually or through some form of collaborative project. In either case, an organization's improvement efforts would be treated as a QAPI project and would be subject to the requirements for such projects set forth in standard 1.4.

1.3 Scope of QAPI Activities. Projects conducted under the organization's QAPI program address and achieve improvement in major focus areas of clinical care and non-clinical services.

1.3.1. Definitions

1.3.1.1. A project is an initiative by the organization to measure its own performance in one or more focus areas, undertake system interventions to improve its performance, and monitor the effect of those interventions.

Assessment of the effectiveness of the organization's QAPI program will be based on review of individual QAPI projects. In the first review year, review will focus on whether the organization has initiated and is actively conducting QAPI projects. In all subsequent years, reviews will focus on completed projects, those that have achieved demonstrable improvement in enrollee health, functional status, or satisfaction. For each project, the organization will be required to supply documentation sufficient to assess the extent to which the project meets the applicable standards of section 1.4.

> **1.3.1.2. A project will be considered to have achieved <u>demonstrable improvement</u> in a focus area during any review year in which an improvement meeting the minimum thresholds of standard 1.4.4 is measured.**

It is not expected that a project initiated in a given year will necessarily achieve improvement in that year. Some—for example, a project focusing on improving long-term survival rates for patients with a given condition—might continue for many years before it would be possible even to measure the effect of the organization's interventions. However, such a project would not be counted as achieving improvement until the year in which the necessary level of improvement is demonstrated. (An exception for certain multi-year projects is provided under standard 1.3. 8.2.)

> **1.3.1.3. For the purpose of standard 1.3.2.1, the first <u>review year</u> is, in the case of an organization with a Medicare or Medicaid contract in effect on the date these standards are put into effect by HCFA or the State Medicaid agency, the year beginning on that date. For an organization that first enters into a Medicare or Medicaid contract after the date these standards are adopted by HCFA or the State Medicaid agency, the first review year is the year beginning on the effective date of that contract.**

All subsequent review years begin on the anniversary of the beginning of the first review year. Note that review years are <u>not</u> defined in terms of the dates on which reviews are actually conducted. There may be instances in which an organization completes a project after the end of a review year but before the review for that year is conducted. In this case, the organization may ask that the project be considered in the review for the past review year, provided that all necessary documentation is available at the time of the review. (Of course, the project would then not be counted toward requirements for the subsequent year.)

> **1.3.2. Phase-In and Scope. An organization meets the requirements of this section if—**

This standard establishes a four-year phase-in period, during which each organization must gradually broaden the scope of clinical and non-clinical areas in which improvements are achieved through its QAPI program. Tables 1 and 2 summarize the Medicare and Medicaid requirements for clinical and non-clinical areas in the phase-in period and later years.

Table 1. Phase-In of Required Improvements In Clinical Focus Areas

Medicare	Medicaid
Clinical Focus Areas	Clinical Focus Areas
1. Prevention	1. Prevention for adults
2. Chronic disease	2. Prenatal care
3. Inpatient care or ambulatory surgery	3. Well-child care
4. Long-term care (LTC) facility residents	4. Ambulatory care, families and children
5. Dependent (outside LTC facility)	5. Chronic disease, elderly or disabled
6. Mental health treatment	6. Inpatient care or ambulatory surgery
7. Substance abuse treatment	7. Long-term care (LTC) facility residents
	8. Dependent (outside LTC facility)
	9. Mental health treatment
	10. Substance abuse treatment
	11. Care of developmentally disabled

Review Year	Number of Focus Areas for Improvement	Review Year	Number of Focus Areas for Improvement
1	0[1]	1	0[1]
2	2	2	2
3	3	3	3
4	4	4	4
4-5	7	3-4-5	11[2]
5-6	7	4-5-6	11
6-7	7	5-6-7	11
7-8	7	6-7-8	11

[1]Must initiate projects addressing at least two clinical focus areas.
[2]Number reduced if organization's Medicaid contract does not include service or population addressed in a clinical focus area.

Table 2. Phase-In of Required Improvements In Non-Clinical Focus Areas

Non-Clinical Focus Areas (Medicare and Medicaid)

1. Complaints and grievances
2. Denials of authorization or payment for services
3. Cultural competence
4. Availability of desired services
5. Convenience of available services
6. Timeliness of available services

Review Year	Number of Focus Areas for Improvement
1	0[1]
2	2
3	2
4	2
3-4-5	6
4-5-6	6
5-6-7	6
6-7-8	6

[1]Must initiate projects addressing at least two clinical focus areas.

1.3.2.1. By the end of the first review year, the organization has initiated a project or projects addressing any two of the clinical focus areas specified under standard 1.3.3 (in the case of an organization with Medicare enrollees) or 1.3.4 (in the case of an organization with Medicaid enrollees) and any two of the non-clinical areas specified under standard 1.3.5.

A project is deemed to have been initiated when it has proceeded at least to the point of baseline data collection. That is, the organization has selected a particular aspect of care for performance measurement, has identified the statistical indicator or indicators that will be used, and has begun the process of collecting the data needed for an initial assessment of its performance on the indicator(s). Review for the first year will therefore focus on compliance with standards 1.4.1 through 1.4.3.

1.3.2.2. By the end of the second review year, the organization has achieved demonstrable improvement in two clinical focus areas and in two non-clinical areas.

1.3.2.3. During the third review year, the organization achieves demonstrable improvement in three clinical focus areas and two non-clinical areas.

This standard may be met in either of two ways. The organization could achieve improvement in entirely different clinical focus areas from those in which it achieved improvement in the second year. Or it could achieve additional improvement in one or both of the areas in which it achieved improvement in prior years, and also achieve improvement in new focus areas as necessary to meet the requirement for improvement in a total of three areas. (Note that additional improvements are assessed relative to the level achieved in the previous improvement, not relative to the organization's baseline performance; see the guideline for standard 1.3.8.1.) A similar principle applies in the case of non-clinical areas: the organization can achieve a further improvement in a focus area previously addressed or achieve improvement in a new focus area.

1.3.2.4. During the fourth review year, the organization achieves demonstrable improvement in four clinical focus areas and two non-clinical areas.

Again, this standard may be met through a mix of additional improvements in focus areas previously addressed and improvements in new areas. In planning its activities, however, the organization must be conscious of the provisions of the next standard, which requires that improvement in all applicable focus areas be achieved by the end of the fifth review year. An organization that has addressed a narrower range of focus areas during the phase-in years will face a greater burden in the fifth year.

1.3.2.5. By the end of each review year after the fourth review year–

1.3.2.5.1. the organization has, during the preceding three years, achieved demonstrable improvement in each of the non-clinical focus areas specified under standard 1.3.5;

In this and the next two standards the multi-year periods are rolling, rather than fixed. That is, an organization whose fifth review year is calendar year 2003 must have achieved improvements in all six non-clinical areas during the period 2001-2003, the period 2002-2004, and so on. If the organization achieved an improvement in a given area in January 2001, it would be in compliance if its second improvement occurred at any time before the end of December 2004, because it would have an improvement for the 2001-2003 period and for the 2002-2004 period. However, if its second improvement did not occur until January 2005, it would not be in compliance, because no improvement would have occurred in the three review years 2002-2004.

In order to assure that it meets the requirement for at least one instance of demonstrable improvement in each focus area in each rolling three-year period, an organization may need to conduct multiple projects, in case one or more projects fail to produce improvement of the magnitude required under standard 1.4.4. Or it may need to set goals for its projects in such a way that even projects that fall short of their targets still meet the minimum thresholds for demonstrable improvement.

> **1.3.2.5.2. an organization with Medicare members has, during the preceding two years, achieved demonstrable improvement in each of the focus areas specified under standard 1.3.3;**
> **1.3.2.5.3. an organization with Medicaid members has, during the preceding three years, achieved demonstrable improvement in each of the focus areas specified under standard 1.3.4.**

Note that Medicare organizations must achieve improvements in all focus areas in each rolling two-year period, while Medicaid organizations must achieve improvements in all focus areas in each rolling three-year period. This is because the Medicaid standards provide for a larger number of clinical focus areas. The standards for Medicaid organizations will require adjustment in the case of organizations that have not contracted to serve all types of Medicaid beneficiaries. An organization that is enrolling only families and children cannot conduct projects in areas 1.3.4.5, 1.3.4.7, and 1.3.4.8. As this leaves only eight clinical areas, a State might modify the timeframe for achieving improvements. For other organizations—such as one serving only the frail elderly, or only persons with HIV disease—the State might drop some irrelevant focus areas but establish additional relevant ones, or require multiple projects in a key focus area.

> **1.3.2.6. In each review year, an organization with both Medicare and Medicaid members must meet the requirements for an organization with Medicare members and the requirements for an organization with Medicaid members.**

This standard means that an organization with both Medicare and Medicaid contracts must, in the first review year, initiate projects addressing two Medicare clinical areas and two Medicaid clinical areas. This does not mean that the organization must initiate four different projects. As is discussed in the guideline for standard 1.3.6, below, a single project may address more than one focus area and can target both the Medicare and Medicaid populations. In subsequent years, the organization must achieve

improvements for both Medicare and Medicaid enrollees according to the timetables established for each program.

If an organization that initially contracts with one program later contracts with the other, the timetables for improvements run separately. For example, if an organization first contracted with Medicare on January 1, 2000, and with Medicaid on January 1, 2002, then in 2002 it would be in its third Medicare review year and its first Medicaid review year.

1.3.3 Medicare clinical focus areas. Clinical focus areas applicable to Medicare enrollees are as follows:

Note that the comments under each of the following focus areas are meant to clarify the intended emphasis for each area and, in some instances, to furnish examples of possible project topics. The aim is not to limit the plan's discretion to select its own appropriate topics, taking into account its own population needs, performance on standard measures, and other factors. HCFA encourages innovation in this area and intends to work closely with organizations and State agencies in development of measurement tools and appropriate interventions.

1.3.3.1 Prevention for Medicare enrollees;

Unlike the standard for Medicaid, below, the Medicare standard does not establish distinct prevention focus areas for different subgroups of Medicare beneficiaries. However, it is HCFA's expectation that project topics will be selected in such a way as to assure that efforts to improve preventive care reach the entire Medicare population to the extent feasible. For example, a project focusing on mammographies or pap smears would need to be balanced with a project addressing the needs of male enrollees, such as one on prostate exams. Or a project could extend to the entire population (e.g. a project on flu immunizations). Projects in this focus area could also undertake to improve the rate of identification and referral of enrollees with specific problems or requiring specific services. For example, a project could seek to improve detection of mental health or substance abuse problems by medical care practitioners.

1.3.3.2 Chronic diseases affecting Medicare enrollees;

A project in this area should focus on issues in ongoing management of a chronic condition (e.g., diabetes), rather than simply on identification of the condition. Note that a project in this area cannot focus solely on issues in mental health or substance abuse services, although a broad project on management of chronic problems could include these areas as well as services for medical conditions.

1.3.3.3 Care of Medicare enrollees receiving hospital inpatient or ambulatory surgery services, including post-discharge care;

To the extent feasible, a project in this area should consider overall care during an episode or spell of illness, including, as relevant, ambulatory care before and after the admission or surgery, discharge planning, and coordination of care across settings.

1.3.3.4 Care of Medicare enrollees residing in long-term care facilities;

Although a Medicare contractor is not financially responsible for long-term custodial care, it remains responsible for management of the overall medical care of enrollees residing in nursing facilities or other long-term care settings. A project could focus on acute care for these residents (e.g., prevention of avoidable transfers to hospitals) or on aspects of their long-term care that can be affected by medical care interventions (e.g., medication management). Or a project could focus on skilled nursing facility services, for which contractors are responsible to the extent these services are covered under Medicare rules.

1.3.3.5 Care of Medicare enrollees who are unusually dependent on others or on devices but who do not reside in long-term care facilities;

This standard is intended to address care of functionally disabled enrollees living in the community. It is recognized that many organizations cannot at this point even readily identify such enrollees, and it will be acceptable for initial projects in this area to focus on screening for disability and referral for appropriate case management and coordination services. Over time, however, it is expected that all organizations will be able to identify their functionally disabled enrollees and will shift their focus in this area to actual improvement of outcomes, such as improved maintenance of functional status and independence.

1.3.3.6 Mental health treatment for Medicare enrollees; and
1.3.3.7 Substance abuse treatment for Medicare enrollees.

Projects in either of these areas may focus on outcomes of mental health or substance abuse treatment or on coordination of these services with overall medical care. As was noted above, some organizations may wish to undertake projects to improve the rate of identification and referral of enrollees requiring mental health or substance abuse services by medical care practitioners. However, such a project would be considered as falling within the preventive care focus area (1.3.3.1), and would not be considered as addressing these focus areas unless the project also produced improvement in actual outcomes of treatment.

1.3.4 Medicaid clinical focus areas. Clinical focus areas applicable to Medicaid enrollees are as follows:

As was noted earlier, the following delineation of Medicaid focus areas assumes that an organization is enrolling all Medicaid populations and providing the full scope of Medicaid covered services (usually excluding long-term custodial care). The list of focus areas, or their definitions, should be modified as appropriate when specific services are excluded from an organization's contract. For example, some States have "carved out" mental health and substance abuse services; enrollees requiring these services obtain them through a distinct Medicaid contractor, rather than through the organization that provides their general medical care. A State might still wish to retain one or both of these focus areas for general medical organizations, with an emphasis on improving referral for and coordination with mental health and substance abuse

services. Similar considerations may apply to other arrangements in which an organization's contract is less than comprehensive. For example, if a State used these standards to review organizations at risk only for ambulatory services, it might still choose to promote improved coordination and patient management by retaining a focus area for inpatient care.

It is recognized that three distinct prevention areas (considering prenatal care as prevention) have been defined for Medicaid, as opposed to one for Medicare. There are several reasons for this. First, Medicaid serves several distinct populations with different preventive care needs; it is important that none of these populations be neglected. Second, many Medicaid contractors are likely to be exempt from one or more of the non-preventive focus areas, because of the populations served or a limited scope of contracted services; for these organizations, the actual number of required areas may not be greater than for Medicare organizations.

1.3.4.1 Prevention for adult Medicaid enrollees;

The target population for this area includes adults receiving Aid to Families with Dependent Children (AFDC) or Temporary Assistance to Needy Families (TANF) and, if enrolled, elderly and disabled enrollees. The topic must be some aspect of prevention other than prenatal care.

1.3.4.2 Prenatal care for pregnant Medicaid enrollees;

This area may initially be defined as focusing on access to and timely initiation of prenatal care, because of the continuing technical difficulties in developing usable, risk-adjusted measures of pregnancy outcomes. As usable measures become available, organizations will be expected to shift their focus to improvement of these outcomes.

1.3.4.3 Well-child care for Medicaid enrollees who are children or adolescents;

This area includes immunizations, screenings, and other components of Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) services.

1.3.4.4 Ambulatory care for Medicaid enrollees who are enrolled under family or child categories;

This area is defined in terms of eligibility category simply to clarify that the focus should be on care for conditions common among Medicaid children and adults who are not elderly or disabled (even though there are many adult recipients of AFDC or TANF who are elderly or disabled). A project focusing on a condition that was more prevalent among the elderly or disabled would be considered as addressing focus area 1.3.4.5, rather than this one.

1.3.4.5 Chronic diseases affecting elderly or disabled Medicaid enrollees;

1.3.4.6 Care of Medicaid enrollees receiving hospital inpatient or ambulatory surgery services, including post-discharge care;

See 1.3.3.2 and 1.3.3.3.

1.3.4.7 Care of Medicaid enrollees residing in long-term care facilities;

See 1.3.3.4, except that, in the case of an organization that is at risk for long-term care services, improvement in actual nursing facility care (e.g., reduction in restraint use) would be an appropriate topic.

1.3.4.8 Care of Medicaid enrollees who are unusually dependent on others or on devices but who do not reside in long-term care facilities;

Organizations enrolling only families and children should focus on care of children with special needs.

1.3.4.9 Mental health treatment for Medicaid enrollees;
1.3.4.10 Substance abuse treatment for Medicaid enrollees; and
1.3.4.11. Care of Medicaid enrollees who are developmentally disabled.

As in the case of mental health and substance abuse services, some States have "carved out" services for developmental disabilities; enrollees requiring these services obtain them outside the organization. Other states may not enroll persons with developmental disabilities in managed care arrangements at all; their overall care continues to be coordinated by the facilities and/or community targeted at this population. A State that includes services for developmental disabilities in its contracts with organizations should require this focus area. A State that allows enrollment of beneficiaries with developmental disabilities in general medical organizations but does not include services for developmental disability in the contracts might still wish to retain this focus areas, again with an emphasis on improving referral for and coordination with developmental disability services.

1.3.5 Non-clinical focus areas. Non-clinical focus areas applicable to both Medicare and Medicaid enrollees are as follows:

1.3.5.1 Complaints and grievances;
1.3.5.2 Denials of authorization or payment for services;

Projects related to the grievance and coverage determination processes may aim either to improve the processes themselves or to address an underlying issue in care or services identified through analysis of grievances or appeals. For example, an organization with a high rate of grievances not resolved until the third or fourth step in its grievance procedure might focus on how grievances are addressed in the initial phases of the process. An organization with a high rate of grievances related to one particular type of service might instead focus on improvements in access to or delivery of that service. Similarly, an organization with a high rate of adverse determinations overturned by the Medicare independent reconsideration contractor, or by the State

agency administering the State appeals program, might aim to reduce this rate by improving its procedures for initial review of authorization requests. An organization with a high rate of sustained adverse determinations (for example, denials of inappropriate emergency room care) might instead focus on measures to improve provider and enrollee understanding of its procedures for obtaining covered services.

1.3.5.3 Cultural competence;

Cultural competence is the knowledge and interpersonal skills that allow individuals in organizations to understand, appreciate, communicate, and work with people from cultures other than their own. For persons seeking services from organizations, cultural competence results in a feeling or impression of safety, respect, and ease. In a medical model, cultural competence includes the attainment of knowledge, skills, and attitudes that enable administrators and practitioners within systems of care to provide an support effective health care delivery for diverse populations.

By targeting QAPI projects in the area of cultural competence, it is anticipated that access to covered services will improve and that use of covered health care services will become more appropriate while disparities in outcome of care will decrease. The following is a preliminary discussion of possible activities in this area. A document providing more detailed guidance is under development and will appear as an appendix to the final draft of these guidelines.

Focuses may include: increasing the ratio and distribution of minority physicians and/or allied health professionals in an organization to the population served; analyzing and improving scores on effective communication as demonstrated in patient satisfaction surveys; developing QAPI projects that examine the effectiveness of an outreach program for a specific population in conjunction with population-based measures of a specific disease; improving overall satisfaction among a population that may be represented disproportionately in the organization; or improving the utilization rates among minority patients for various disease management programs.

1.3.5.4 Availability of desired services;
1.3.5.5 Convenience of available services; and
1.3.5.6 Timeliness of available services.

Projects in these three areas should focus on assessing and improving the accessibility and availability of specific services or services for specific conditions.

Standard 3.1.1.2 requires the organization to develop its own general standards of access and availability for all services and continuously monitor its own compliance with these standards. The organization would be expected to take prompt administrative action to address deficiencies or gaps in its provider network identified through this ongoing monitoring. For example, a finding that enrollees had long waits for appointments for a specific service because an insufficient number of providers were available would properly be addressed through the organization's provider recruitment function and not through a QAPI project.

QAPI projects in these areas should instead emphasize, as in other focus areas, improvement in outcomes, addressing access and availability of care as these may affect health or functional status or member satisfaction. For example, a project might focus on reduction of inpatient admissions for ambulatory sensitive conditions (those for which timely ambulatory care may prevent inpatient admissions). Or it might address the promptness with which referral services are furnished in response to a positive result on a given diagnostic test.

1.3.6 Multiple focus areas. A single project may be considered as addressing more than one required focus area, or as addressing services for both Medicare and Medicaid enrollees, so long as the project meets the requirements of standard 1.4 for each focus area and/or population addressed.

The standards in this section are not intended to dictate a minimum number of projects to be conducted by an organization, but to assure that the organization's QAPI activities do not focus on one or two aspects of care or services and neglect the others entirely. Organizations are encouraged to develop projects that span focus areas. This could occur in at least two ways:

- A project related to a specific condition might span settings or modalities of care for that condition. For example, a project on diabetes might address both acute episodes and long-term management, and thus address both the inpatient care (1.3.3.3) and chronic care (1.3.3.2) areas.

- A project related to care in a given setting might address care of enrollees with a variety of conditions. For example, a project to improve continuity of care following inpatient hospital discharges might consider care for both medical/surgical and mental health/substance abuse discharges. It would then address focus areas 1.3.3.3, 1.3.3.6, and 1.3.3.7. However, a project that focussed solely on mental health/substance abuse cases would be considered as addressing only the mental health and substance abuse focus areas, not the general inpatient care focus area 1.3.3.3.

Similarly, organizations are encouraged to develop projects that span the Medicare and Medicaid (and commercial) populations. However, the organization must show that the topic to be addressed is significant for both groups. For example, it might not be appropriate for an organization whose Medicaid enrollment was restricted to families and children to conduct a joint Medicare/Medicaid project on treatment of cardiac patients, because only a small proportion of its Medicaid enrollees would fall into this category.

1.3.7. Special Projects

1.3.7.1. Alternative focus areas. An organization may propose alternative focus areas to HCFA or to the State Medicaid agency, or HCFA or the State agency may designate alternative focus areas for any organization or multiple organizations.

The focus areas specified in standards 1.3.3 through 1.3.5 are intended to highlight key components of care and services for organizations serving a typical Medicare or Medicaid population. There may be instances in which either the organization, or HCFA or the Medicaid agency, believes that some aspects of care require greater emphasis, either because of special population needs or because the organization's performance is in need of greater improvement in some areas than in others. In this case, it may be appropriate for an organization to conduct more work in one area and none in some others, or to develop a distinct focus area that does not readily fit under any of the listed categories. This standard provides for such alternatives, with the prior approval of, or at the request of, HCFA or the Medicaid agency. Alternative focus areas may also be approved when an organization has so few enrollees requiring a specific type of care that a project focusing on this aspect of care would not be meaningful.

1.3.7.2. Collaborative projects. Organizations may satisfy the requirements of standard 1.3.2 by participating in collaborative projects, subject to the approval of HCFA or the State Medicaid agency.

Some State Medicaid agencies and HCFA have encouraged collaborative efforts, under which several contracting organizations undertake a joint quality improvement project addressing a common topic. These standards would not preclude such collaborative efforts under either Medicare or Medicaid. Any such initiative would be individually evaluated, and HCFA or the State agency would establish criteria for assessing the extent to which each organization's participation constituted compliance with these standards. For example, if several organizations conducted a joint project to improve childhood immunization rates, the State might determine that all participating organizations would be considered as having addressed the focus area that is the subject of the project. However, the State would also need to decide how improvement should be measured. If aggregate immunization rates for the entire target population improved, would all participating organizations be considered as having achieved improvement, or would the improvement for each participant have to meet the minimum thresholds specified in standard 1.4.4? These guidelines do not establish a uniform principle for this kind of question; the appropriate answer will depend on features of the particular project (such as whether interventions involve administrative changes in each individual organization or changes in the practice patterns of practitioners who serve enrollees of multiple organizations).

1.3.8. Multi-year projects. If a project is conducted over a period of more than one review year—

1.3.8.1. The project will be considered as achieving improvement in each year for which it achieves an improvement meeting the requirements specified in standard 1.4.4;

An organization may continue a project that has already been determined to have achieved demonstrable improvement. If further improvement occurs, the project may again be considered to have achieved demonstrable improvement. However, the improvement will not be measured relative to the original baseline, but relative to the improved performance level previously scored. For example, an organization could meet standard 1.4.4 in Year One by reducing its percentage of non-immunized children

from a baseline of 20 percent to a level of 18 percent. It could continue the project for an additional year, and could meet the standard again in Year Two by reducing the percentage of non-immunized children to 16.2 percent. It is not necessary that the improvements be achieved in successive years for a project to be counted in this way. For example, a four-year project might achieve the 18 percent level in its second year, 17 percent in its third year, and 16 percent in its fourth year. It would then be considered as having achieved demonstrable improvement in the second and fourth years; the improvement in the third year would not be counted because it did not represent a 10 percent reduction from the previously scored level of 18 percent.

1.3.8.2. A project may be considered as achieving improvement in each year for which it achieves an improvement that does not meet the requirements specified in standard 1.4.4, but that constitutes an intermediate target specified in a project work plan developed in consultation with HCFA or the State Medicaid agency.

An organization may undertake a particularly complex or difficult project that is not expected to achieve demonstrable improvement, as defined under standard 1.4.4, for several years. This might occur because:

- Improvement in the targeted outcome cannot be measured for a long period; for example, the organization wishes to improve five-year survival rates for breast cancer.

- Improvement in outcomes can come only after process improvements that are not closely enough related to outcomes to meet the requirement of standard 1.4.3.2.

- Improvement will require multiple system interventions that cannot be implemented over a short period.

Such a project would not ordinarily be counted as achieving improvement until an improvement in outcomes meeting the thresholds of standard 1.4.4 could be documented. The organization would then need to conduct other projects in the same focus area that achieve improvement more rapidly, because of the requirement that improvement be achieved in each focus area during any two-year (for Medicare) or three-year (for Medicaid) period. This standard creates an exception for certain multi-year projects with measurable interim goals.

Prior approval is not required for such a project. However, an organization that anticipates that it will meet the minimum requirements of this standard for a review year only if a multi-year project is counted may request advance review of the project plan at the time the project is initiated. A multi-year project may be approved under the following circumstances:

1. The timetable for the project is reasonably related to the complexity of the project or the length of time that must elapse before the outcomes of the project can be assessed. There must be a clear and defensible reason for defining a project as a multi-year project.

2. There must be significant ongoing activity related to the project during each of the review years for which the project is to be counted. For example, while a project that involves a one-time system change that is expected to affect five-year survival rates cannot measure its success until five years have elapsed, it will not necessarily be considered as an ongoing project during each of the intervening years. It would be treated as ongoing only if it provided for continuous data collection throughout the project period, along with ongoing efforts to identify and implement system changes aimed at improving the long-term outcome.
3. The project must specify some form of quantifiable interim goals or intermediate outcomes for each project year, so that it is possible to monitor the continuing progress of the project. For example, an organization conducting a project on breast cancer survival rates might track a process of care (such as mammography screening rates) or an intermediate outcome (such as stage of breast cancer at detection) and set goals for each year of the project.

1.4 Assessment of QAPI Projects

An individual project involves identification of an aspect of clinical care or non-clinical services to be studied; specification of quality indicators to measure performance in the selected area; collection of baseline data; identification and implementation of appropriate system interventions to improve performance; and repeated data collection to assess the immediate and continuing effect of the interventions and determine the need for further action.

- Standard 1.4.1 measures the relevance and importance of each project conducted by an organization.

- Standards 1.4.2 and 1.4.3 assess the meaningfulness of the specific performance indicators selected for measurement in an individual project and the validity and reliability of the measurement.

- Standards 1.4.4 evaluates the extent to which a project resulted in demonstrable and sustained improvement.

An individual project is regarded as successfully completed only if it meets each of the standards, 1.4.1 through 1.4.4. Because the key project components identified in those standards are interdependent, failure on any one of them invalidates the entire project. For example, if the organization chooses to measure its performance on quality indicators that have no likely relation to outcomes, improvement in the indicators cannot be expected to improve health or functional status. If the organization cannot collect reliable data, it cannot demonstrate improvement, and so on. The organization's summary of a completed project must document compliance with each standard.

> **1.4.1 Selection of topics. Within each required focus area, the organization selects a specific topic or topics to be addressed by a project.**

1.4.1.1 Topics are identified through continuous data collection and analysis by the organization that reflects all aspects of patient care and member services.
1.4.1.2 Topics are systematically selected and prioritized to achieve the greatest practical benefit for enrollees.
1.4.1.3 Selection of topics takes into account: the prevalence of a condition among, or need for a specific service by, the organization's enrollees; enrollee demographic characteristics and health risks; and the interest of consumers in the aspect of care or services to be addressed.

This standard relates to focus areas for projects selected by the organization itself. Projects conducted at the specific direction of HCFA or the Medicaid agency will be deemed to have met this standard.

Reports of completed projects must document the basis on which the organization selected project topics. The selection of topics for studies must be based on: continuing monitoring of population needs and preferences and organizational performance; identification of areas of concern; and clear criteria, identified by the organization, for prioritizing the areas to be addressed.

As standards 1.6.3 and 1.6.4 indicate, the organization's affiliated providers must have a formal opportunity to participate in the selection and prioritization of QAPI projects.

Sources of information

The QAPI program must routinely collect and interpret information from all parts of the organization, to identify areas of clinical concern, health delivery system issues, and issues in member services. Types of information to be reviewed include:

- Population information. Data on enrollee characteristics relevant to health risks or utilization of clinical and non-clinical services, including age, sex, race/ethnicity/language, and disability or functional status.
- Performance measures. Data on the organization's performance as reflected in standardized measures, including when possible local, state, or national information on performance of comparable organizations.
- Other utilization, diagnostic, and outcome information. Data on utilization of services, procedures, medications and devices; admitting and encounter diagnoses; adverse incidents (such as deaths, avoidable admissions, or readmissions); and patterns of referrals or authorization requests.
- External data sources. Data from outside organizations, including Medicare or Medicaid fee-for-service data, data from other health plans, and local or national public health reports on conditions or risks for specified populations. (In newly formed organizations, or organizations serving a new population, external data may be the major source of potential project topics.)
- Enrollee satisfaction information. Data from surveys (such as the Consumer Assessment of Health Plans Study, or CAHPS), information from the grievance and appeals processes, and information on disenrollments and requests to change

providers. (Note that general population surveys may under-represent populations who may have special needs, such as linguistic minorities or the disabled. Assessment of satisfaction for these groups may require oversampling or other methods, such as focus groups or enrollee interviews.) The QAPI program should assess, in addition to information generated within the organization, information supplied by purchasers, such as data on complaints and disenrollments processed by the Medicaid agency.

The QAPI program's project selection process must explicitly take into account quality of care concerns identified by a quality review and improvement organization (QIO) or external quality review organization (EQRO). While it is not expected that each such concern will be addressed through a formal QAPI project meeting the requirements of these standards, the organization should be able to show that concerns were considered in the formulation of its QAPI program agenda and that alternative remedial action is taken in cases for which a QAPI project is not initiated.

Prioritizing topics

In general, topics for projects should relate to conditions or services that are high-volume and high-risk. A clinical or non-clinical issue selected for study should affect a substantial portion of the organization's Medicare or Medicaid enrollees (or a specified subpopulation of enrollees) and have a potentially significant impact on enrollee health, functional status, or satisfaction. There may be instances in which less frequent conditions or services warrant study, as when data show a pattern of unexpected adverse outcomes; however, the prevalence of a condition or volume of services involved must be sufficient to permit meaningful study.

A project topic may be suggested by patterns of inappropriate utilization—for example, frequent use of the emergency room by enrollees with a specific diagnosis. However, the project must be clearly focused on identifying and correcting deficiencies in care or services that might have led to this pattern, such as inadequate access to primary care, rather than on utilization and cost issues alone. This is not to say that the organization may not make efforts to address overutilization, but only that such efforts might not be considered QAPI activities for the purpose of assessing compliance with these standards, unless the primary objective is to improve health outcomes. Thus it would be acceptable for a project to focus on patterns of overutilization that present a clear threat to health or functional status, for example because of a high risk of iatrogenic problems or other adverse outcomes.

Because the achievement of demonstrable improvement is a central criterion in the evaluation of QAPI projects, projects must necessarily focus on areas in which meaningful improvement can be effected through system interventions by the organization. It will therefore generally be advisable for the organization to avoid projects that focus on clinical areas in which outcomes are largely dictated by factors that are unlikely to be influenced by delivery system changes. Most organizations are likely to give priority to areas in which there is significant variation in practice and resulting outcomes within the organization, or in which the organization's performance as a whole falls below acceptable benchmarks or norms.

It is recognized that the requirement for demonstrable improvement creates incentives for organizations to focus all of their QAPI activities on aspects of care in which rapid and measurable improvement is possible through simple interventions. It is not the intention of these standards to discourage organizations from undertaking more complex projects or innovative projects that have a high risk of failure but that offer some offsetting potential for making a significant difference in the health or functional status of enrollees. Organizations considering such projects should avail of themselves of the opportunity, under standard 1.3.8.3, to work in consultation with HCFA or the State agency to develop long-range goals for projects and set agreed upon criteria for evaluation of the organization's progress in implementing its project.

Organizations using physician incentive plans

An organization that adopts a physician incentive plan that places physicians at substantial financial risk (as defined in 42 CFR 417.479(f)) for the care of Medicare or Medicaid enrollees must include in its QAPI process continuous monitoring of the potential effects of the incentive plan on access or quality of care. This monitoring should include assessment of the results of surveys of enrollees and former enrollees required under 42 CFR 417.479(g). In addition, the organization should review utilization data to identify patterns of possible underutilization of services that may be related to the incentive plan (such as low rates of referral services ordered by physicians at risk for the cost of such services). Concerns identified as a result of this monitoring should be considered in development of the organization's focus areas for QAPI projects.

1.4.1.4. The QAPI program provides opportunities for enrollees to participate in the selection of project topics and the formulation of project goals.

The organization must establish some mechanism for obtaining enrollee input on the priorities for its QAPI program. Possibilities could include enrollee representation on a quality assurance committee or subcommittees or routine inclusion of QAPI issues on the agenda for a general enrollee advisory committee. To the extent feasible, input should be obtained from enrollees who are users of or concerned with specific focus areas; for example, priorities in the area of mental health or substance abuse services should be developed in consultation with users of these services or their families.

1.4.2 Quality indicators. Assessment of the organization's performance for each selected topic is measured using one or more quality indicators.

1.4.2.1 Quality indicators are objective, clearly and unambiguously defined, and based on current clinical knowledge; when generally accepted indicators are applicable to the topic, use of those measures is preferred.

Each QAPI project must establish one or more quality indicators that will be used to track performance and improvement over time. An indicator is a variable reflecting either a discrete event (an older adult has/has not received a flu shot in the last 12

months) or a status (an enrollee's hypertension is/is not under control). In either case, an indicator must be clearly defined and subject to objective measurement.

An organization may adopt standard indicators from outside sources, such as HEDIS or FACCT measures, or develop its own indicators on the basis of clinical literature or findings of consensus panels. When the organization develops its own indicators, it must be able to document the basis on which it adopted an indicator; it should be able to show that the process included consultation with affiliated providers and enrollees to assure that measures are meaningful, relevant to the organization's enrolled population, and reflective of community standards of practice.

An organization is not required to select specific indicators at the outset of a QAPI project. There may be instances in which a project would begin with more general collection and analysis of baseline data on a topic, and then narrow its focus to more specific indicators for measurement, intervention, and reevaluation. The success of the project will be assessed in terms of the indicators ultimately selected.

> **1.4.2.2. All indicators measure outcomes: that is, changes in health status, functional status, and/or satisfaction. Measures of processes are used as a proxy for outcomes only when those processes have been established through published studies or a consensus of relevant practitioners to be significantly related to outcomes.**

The object of the QAPI program is to improve outcomes, defined as objective measures of patient health, functional status, or satisfaction following the receipt of care or services. Under this definition, measures of the use of services, costs, or other administrative results do not constitute outcomes. It is recognized, however, that relatively few standardized performance measures actually address outcomes. For example, of the 16 effectiveness measures in HEDIS 3.0, only two (low birthweight babies and health of seniors) are truly outcome-related. Even when outcome measures are available, their utility as quality indicators for QAPI projects may be limited because outcomes are largely dictated by factors outside the organization's control. In other instances—low birthweight babies may be an example—improvement is possible, but the resources and sophistication needed to analyze the complex factors involved in the outcome and develop meaningful interventions might be beyond the reach of many organizations.

This standard therefore does not require that quality indicators be outcome measures. Process measures are acceptable so long as the organization can show that there is strong clinical evidence that the process being measured is meaningfully associated with outcomes. To the extent possible, this determination should be based on published guidelines that support the association and that cite evidence from randomized clinical trials, case control studies, or cohort studies. A plan may furnish its own similar evidence of association between a process and an outcome so long as this association is not actually contradicted by a published guideline. Although published evidence is generally required, there may be certain areas of practice for which empirical evidence of process/outcome linkage is limited. At a minimum, the organization must be able to demonstrate that there is a consensus among relevant practitioners as to the importance of a given process.

1.4.2.3. Indicators selected for a topic in a clinical focus area (under standard 1.3.3 or 1.3.4) include at least some measure of change in health status or functional status and may also include measures of satisfaction.

While organizations are encouraged to consider enrollee satisfaction as an important aspect of care in any of clinical areas listed in standards 1.3.3 and 1.3.4, improvement in satisfaction must not be the sole demonstrable outcome of a project in any of these areas. Some improvement in health or functional status must also be measured. (Note that this measurement can rely on enrollee surveys that address topics in addition to satisfaction. For example, self-reported health status may an acceptable indicator. Or reduction in school absence could be used as an indicator of functional status in children.) For projects in the non-clinical areas, use of health or functional status indicators is generally preferred, particularly for projects addressing access and availability. There may be some non-clinical projects for which enrollee satisfaction indicators alone are sufficient.

1.4.2.4. The organization selects some indicators for which data are available that allow comparison of the organization's performance to that of similar organizations or to local, state, or national benchmarks.

As is discussed under standard 1.4.4, demonstrable improvement may be defined either as reaching a specific benchmark or as improving performance by a fixed percentage amount. While the latter form of improvement is acceptable for the purpose of standard 1.4.4, an organization that works only towards incremental improvements relative to its own past performance can never determine that its performance is optimal—or even minimally acceptable relative to prevailing standards in the community. Whenever possible, then, an organization should select indicators for which data are available on the performance of other comparable organizations (or other components of the same organization), or for which there exist local or national data on typical practice patterns for a similar population in the fee-for-service sector. Because the availability of such data will vary by topic and by population, this standard does not set a fixed number of focus areas for which benchmarks must be adopted. However, every organization should be able to establish benchmarks for at least some project topics (e.g., immunizations or initiation of prenatal care).

1.4.3 Data collection and methodology. Assessment of the organization's performance on the selected indicators is based on systematic, ongoing collection and analysis of valid and reliable data.

Assessment of compliance with this standard will be coordinated with review of the organization's information systems under standard 1.5.

1.4.3.1 The organization establishes a baseline measure of its performance on each indicator, measures changes in performance, and

continues measurement for at least one year after a desired level of performance is achieved.

Reports on completed QAPI projects must include a detailed account of the data collection methodology used and the procedures through which the organization has assured that the data are valid and reliable. [NOTE: if the indicator selected for a QAPI project is a performance measure that the organization is required to report routinely to HCFA or a State Medicaid agency, review of compliance in this area might be coordinated with whatever validation process HCFA or the State establishes for such reporting.]

Methodology

Most quality indicators are reported in terms of percentages or ratios; for example, the percentage of pregnant women who begin prenatal care in the first 13 weeks of the pregnancy. An organization adopting this measure must show that it can accurately compute the relevant denominator or population at risk (all pregnant women) and the numerator or indicator (pregnant women beginning prenatal care in the specified time frame).

Identification of the population at risk requires particular scrutiny. For some indicators, the population can be identified in readily available administrative data (all children under age 2, or all inpatient discharges with a diagnosis of heart attack). For others, needed data may be unavailable or unreliable. For example, even in an organization that collects individual encounter data, this data might not be usable to identify all enrollees with diabetes, because physicians may not report ongoing conditions at every encounter. Instead the organization must identify the population at risk through direct review of medical records.

The organization must, then, clearly specify what data are used to identify the population at risk and show that these data can reliably capture the entire population. The organization may study a sample of the relevant population (as would be likely if the population of diabetics were to be identified through chart review). If so, it must show that the sample size is sufficient to achieve an appropriate level of confidence (see standard 1.4.4.4) and that the sampling method is such that all members of the population are equally likely to be selected. (This will generally mean random sampling, although stratified random sampling may be appropriate when the intent is to compare care by different practitioners or at different sites.)

In addition to assuring that data collection is adequate and appropriate, the study methodology may need to address other issues in the computation of the indicator. For example, when an indicator relates to receipt of a specific service, the denominator may need to be adjusted to reflect instances in which the patient refuses the service or the service is contraindicated. Similar problems may affect the numerator. For example, in a study of immunization rates, the organization would need to establish how it would detect and account for instances in which immunizations were received at school or at a health department, rather than through the primary care practitioner.

Validation

Data will most commonly be derived from administrative data generated by the organization's health information system or from review of medical records. (In

assessing non-clinical services, other sources such as enrollee or provider surveys may be appropriate.)

When data are derived from the health information system, their reliability is obviously a function of the general reliability of the system. In this case, assessment of compliance with this standard will be coordinated with review of compliance with the information system requirements in standard 1.5.

When data are derived from direct review of medical records or other primary source documents, steps must be taken to assure that the data are uniformly extracted and recorded. Appropriately qualified personnel must be used; this will vary with the nature of the data being collected and the degree of professional judgment required. There must be clear guidelines or protocols for obtaining and entering the data; this is especially important if multiple reviewers are used or if data is collected by multiple subcontractors. Inter-reviewer reliability should be assured through, for example, repeat reviews of a sample of records.

Note that all data collection for QAPI projects is subject to the confidentiality requirements of standard 2.2.1.

1.4.3.2 Sampling methodology for assessment of the organization's performance shall be such as to assure that the data collected reliably reflect the performance of all practitioners and providers who serve Medicare or Medicaid enrollees and whose activities are the subject of the indicator.

Once a topic has been selected, the organization must assure that its measurement and improvement efforts are system-wide. Each project must, to the extent feasible, reach all providers in its network who are involved in the aspect of care or services to be studied. This standard does not establish a requirement that an organization review the performance of each and every provider who furnishes the services that are the subject of the project. Sampling is acceptable so long as the organization assures that its samples are genuinely random. The organization must be able to show that:

- Each relevant provider has a chance of being selected; no provider is systematically excluded from the sampling;

- Each provider serving a given number of enrollees has the same probability of being selected as any other provider serving the same number of enrollees; and

- Providers who were not included in the sample for the baseline measurement have the same chance of being selected for the follow-up measurement as providers who were included in the baseline.

This standard is, of course, easier to meet if the organization selects for study a condition that affects relatively few of its enrollees or is treated by a limited number of providers. However, the organization might then be unable to show that its selection of topics meets the criteria in standard 1.4.1, including the core requirement that topics be selected so as to achieve the greatest practical benefit for enrollees.

1.4.4 Demonstrable and sustained improvement. The organization's interventions result in improvement in the selected quality indicator(s) that is significant and sustained over time.

1.4.4.1 The organization (a) achieves a benchmark level of performance that is defined in advance by the organization (or by HCFA or the State Medicaid agency), or (b) achieves a reduction of at least 10 percent in the number of enrollees who do not achieve the outcome defined by the indicator (or, if applicable, in the number of instances in which the desired outcome is not achieved).

The organization must demonstrate, through repeated measurement of the quality indicators selected for the project, meaningful change in performance relative to the performance observed during baseline measurement. The repeat measurement should generally use the same methodology as the baseline measurement, except that, when baseline data was collected for the entire population at risk, the repeat may instead use a reliable sample.

Benchmark. The organization may establish a benchmark that exceeds its baseline level of performance and that reflects performance in other organizations, local or national norms as established through comparative data, or reasonable expectations of optimum performance. The organization must be able to document the basis on which its benchmark was determined.

This standard does not prescribe any minimum interval between the baseline and the benchmark. In theory an organization could select an indicator for which it was achieving the desired outcome in 89 percent of cases and set a benchmark of 90 percent (if the organization can document the basis for the 90 percent target). As a practical matter, the last 1 percent improvement may be the most difficult to achieve. In addition, the organization must bear in mind the statistical significance requirement of standard 1.4.4.4. It may not target an improvement too small to be measured with a high degree of confidence.

Percent change. An organization meets this standard if, for example, its child immunization rate is 80 percent in the baseline and increases to 82 percent, because the percentage of children not immunized has dropped from 20 percent to 18 percent, a 10 percent reduction. An organization whose baseline rate was 60 percent would have to reach 64 percent—a reduction in non-immunized children from 40 percent to 36 percent. (Note that, to assure uniform computation of improvement across indicators, all indicators must first be stated in the form of a positive outcome, and improvement measured as a reduction in its inverse.)

The requirement for a 10 percent reduction in adverse outcomes is based on several considerations. First, the use of a constant percentage reflects the likelihood that change is harder to achieve when an organization's baseline performance is already superior. Thus the organization with an 80 percent immunization rate is only expected to achieve a 2 percent improvement, while the organization with a 60 percent rate must achieve a 4 percent improvement. Second, the 10 percent level is consistent with results HCFA has

observed in successful improvement projects sponsored by the agency. Finally, smaller improvements would generally be of little clinical significance.

Note that improvement in an indicator is not necessarily the same as improvement in the health or functional status of enrollees. For example, the "health of seniors" indicator under HEDIS 3.0 will track, over time, changes in the functional status of elderly enrollees. Each enrollee's functional status may remain stable or actually decline. However, an organization would demonstrate improvement on the indicator if it slowed the rate of decline, whether or not it actually improved enrollees' functional status.

1.4.4.2 The improvement is reasonably attributable to interventions undertaken by the organization.

It is expected that interventions resulting from QAPI studies will be system interventions: that is, educational efforts, changes in policies, targeting of additional resources, or other organization-wide initiatives to improve performance. Interventions that might have some short-term effect but are unlikely to induce permanent change (such as a one-time reminder letter to physicians) are insufficient.

The organization is not required to demonstrate conclusively (for example, through controlled studies) that a change in a controlled measure is the effect of its intervention; it is sufficient to show that an intervention occurred that might reasonably be expected to affect the results. Nor is the organization required to undertake data analysis to correct for secular trends (changes that reflect long-run growth or decline in a measure over an extended period of time). To the extent feasible, however, the organization should be able to demonstrate that its data have been corrected for any major confounding variables with an obvious impact on the outcomes. (For example, an organization should not use a baseline measure of asthma admissions during pollen season and then measure an improvement during another season.)

To the extent feasible, interventions should be designed to address any broader underlying system problems uncovered in the analysis, rather than simply to improve performance on a specific indicator. For example, the organization might determine that one factor in poor outcomes for a given condition was an access problem: too few providers in a given specialty or in a given part of the service area. While the immediate intervention might be to recruit additional providers, the finding should also trigger a review of the organization's policies and procedures for ongoing monitoring of network adequacy.

The expectation of system-level intervention is in contrast to that, expressed in some earlier Medicare and Medicaid guidelines on quality assurance activities, that intervention would occur at a provider-specific or patient-specific level. This does not mean that individual instances of substandard care observed in the course of QAPI projects should merely be recorded for statistical purposes and then forgotten. For example, if reviewers identify a specific case in which an enrollee's health is in continuing jeopardy because a given test result has never been followed up, there is clearly an ethical and professional responsibility to assure that the specific needs of that

enrollee are promptly addressed. In other instances, findings of QAPI studies may trigger intensive review of the practice patterns of an individual provider, leading to interventions in the form of counseling, possible contract sanctions, or reporting to appropriate professional disciplinary bodies.

1.4.4.3 The organization demonstrates through continued measurement that its performance is sustained for at least one year at the minimum level required under standard 1.4.4.1.

The organization must conduct a repeat measurement after an interval of at least one year following the measurement on the basis of which demonstrable improvement was reported. The performance level observed in this repeat measurement must exceed the original baseline performance by an amount sufficient to show continued compliance with standard 1.4.4.1. That is, an organization that achieved a 15 percent improvement need not sustain performance at this level, but must at least sustain its performance at the minimum 10 percent level.

Note that a project that has achieved improvement, and under which no further system interventions are undertaken by the organization, will not be regarded as an ongoing project for the purposes of standard 1.3.1 or 1.3.2 during the period that elapses between the measurement of improvement and the repeat measurement. The organization must carefully distinguish between active projects and projects that have been concluded but for which the repeat measurement has not yet been conducted.

As overall compliance with QAPI standards will be measured review year by review year, there is no simple method for penalizing an organization that receives credit for improvements and then fails to sustain them. If an organization completes a project on one topic and then shifts its attention to a project on another topic, the improvement it achieves in the new project cannot simply be discounted. However, a consistent failure to sustain improvements may lead to heightened scrutiny of the organization's QAPI program, including a requirement that the organization implement strategies for assuring maintained levels of performance or requirements that certain projects be continued even after an initial demonstration of improvement.

1.4.4.4. If data collection is conducted for a random sample of the population, baseline and follow-up sampling shall be conducted using the same methodology, and shall demonstrate that an improvement measured under standard 1.4.4.1 is statistically significant with a *p* value of less than 0.05.

In order to measure improvement it is essential that the measures of performance before and after the organization's interventions be comparable. The same methods for identifying the target population and for selecting individual cases for review must be used for both measurements. For example, in a project to improve care of diabetes, it would not be acceptable to draw the baseline sample from a population identified on the basis of diagnoses reported in ambulatory encounter data, and draw the follow-up sample from a population identified on the basis of pharmacy data. In a project to

address follow-up after hospitalization for mental illness, it would not be acceptable to shift from a sampling method under which an individual with multiple admissions could be chosen more than once to a method under which the individual could be chosen only once.

The *p* value method is a method of hypothesis testing commonly used in statistical software packages. It measures the strength of the conviction with which an observer can make a statement about an entire population on the basis of a measurement of a sample population. For example, if a sampling of enrolled children showed that 70 percent had been immunized, the *p* value method could be used to test the hypothesis that the immunization rate for the entire population was less than 70 percent; $p<0.05$ would mean that there was only a five percent chance that fewer than 70 percent of children had been immunized. The *p* method could also be used to test the reverse hypothesis, that the value was actually greater than 70 percent. In the context of measuring an improvement, the organization must apply the *p* value test to both its baseline and follow-up measurements. If the organization reports that it has increased its immunization rate from 70 to 80 percent, it must first show that there was no more than a 5 percent chance that its baseline immunization rate was already above 70 percent. It must then show that there is no more than a 5 percent chance that its follow-up immunization rate is actually below 80 percent.

1.5. Performance Measurement. The organization maintains a health information system that collects, analyzes, integrates, and reports data necessary to measure its performance and to develop and implement its QAPI program.

The organization's health information system is central to its efforts to manage patient care and to assess and improve health care quality and outcomes. Every organization should be able to collect and integrate data from all components of its network, in order to develop a comprehensive picture of enrollee needs and utilization, including changes in these over time. It should be able use these data in its quality assessment and performance improvement program, as well as in other management activities.

While there are numerous reasons for organizations to improve their information system capacities, the overarching goal for both HCFA and State Medicaid agencies is to improve patient care. For this reason, standard 1.5 focuses on the system's capacity to provide the minimal information required to conduct an effective QAPI program that meets the requirements of other standards in this domain.

Although an encounter data system may often be the most efficient means of meeting the requirements of this standard, the organization may use any methods or procedures for data collection, so long as it can demonstrate that its system achieves the objectives of this standard. The organization must be able to document that each of its QAPI activities is based on complete and valid information, however this information is compiled.

1.5.1 The system collects data on enrollee and provider characteristics, and on services furnished to enrollees, as needed to guide the selection of QAPI

project topics (standard 1.4.1) and to meet the data collection requirements for QAPI projects (standard 1.4.3).

Measurement of compliance with this standard will be an integral part of assessment of compliance with standards 1.4.1 and 1.4.3.

Topic selection. The system must provide information needed to identify priority areas for quality improvement. Ideally, an organization's system should be able to generate such information as:

- Longitudinal profiles of treatment or services furnished to enrollees with a specific diagnosis;
- Profiles of referral services ordered by each primary care practitioner;
- Statistical reports on the prevalence of different conditions or diagnoses among a specific group of enrollees, such as Medicare beneficiaries; and
- Prescription medication usage by type of enrollee, by diagnosis, or by prescribing practitioner.

However, review will focus not on these general system capacities, but on the specific methods adopted for prioritizing topics and on the extent to which the method was applied using valid data.

For example, an organization may indicate that it selected a given condition for a QAPI project because the condition affected 30 percent of its Medicare enrollees. If so, it must be able to show how it knows the prevalence of different conditions among its Medicare enrollees. If its administrative data set has incomplete data from half its providers, the organization cannot make this assertion, unless the information has been obtained through sampling or other means. Again, the standard does not impose a general requirement that organizations be able to report the prevalence of all conditions or diagnoses for all enrollees. It requires that the organization have the specific information it needs to carry out its own particular approach to quality measurement and improvement.

Data collection for QAPI projects. The organization must be able to collect valid baseline and follow-up measurements for quality indicators selected for QAPI projects. If, for example, the organization selects as a Medicaid indicator the HEDIS measure on prenatal care in the first trimester it must be able to:

1. Collect and analyze data on inpatient hospital discharges for Medicaid enrollees during the study period, and be able to identify discharges in live births, with appropriate methods for validating live births under different coding schemes;

2. Collect information on live births occurring in any other site, such as birthing centers;

3. Link this data with enrollment information, in order to restrict the measure to women who were continuously enrolled for 45 weeks before, with no more than one 45-day break in enrollment (or 30 days in some States);

4. Either obtain encounter data with sufficient procedural and diagnostic information to establish which women received prenatal care visits meeting the criteria applied by the measure, or conduct a review of a sample of medical records. (If the latter method is used, the organization must obviously be able to determine which, if any, practitioners the woman visited during the period from 6 to 44 weeks prior to delivery.)

Once again, the standard does not require that any of these processes be carried out through any specific type of information system. However, the organization must be able to show how each process was performed and be able to show that all reasonable steps have been taken to assure that the data are complete and reliable. Any project for which an organization cannot demonstrate compliance with this standard cannot be counted towards the requirements of standard 1.3.1 or 1.3.2 for completed projects in the focus area involved.

1.5.2 The organization assures that information received from providers is reliable and complete.

These standards do not require that organizations receive encounter reporting. However, if the organization relies on encounter reporting or aggregate data reporting for any QAPI activity (e.g., counting enrollees who had prenatal care visits), then it must have an ongoing process for assuring the reliability of the data, whether compiled in its own facilities or reported by outside contractors.

1.5.2.1 The organization verifies the accuracy and timeliness of reported data.

If the organization receives individual encounter data directly from providers, it must have a system for comparing reported data to a sample of medical records, to verify the accuracy and timeliness of reporting or transmission. The objective is to assure that, to the extent feasible, there is a one-to-one correspondence between items included in an organization's summary data and specific services entered in medical records or equivalent source documents. (That is, no reported service was not performed, and no service performed was not reported.)

If the organization receives aggregate information, instead of individual patient encounter reporting, from any provider, the organization must approve the provider's own system for collecting, recording, aggregating, and reporting the data, and must assure that the provider has its own mechanisms for validation.

Identified deficiencies in reported data must be addressed through provider education or other corrective action. The organization's process for recredentialing or recontracting with practitioners and providers, under standard 3.5, must specify the

actions to be taken in the event of ongoing failure by a contractor to meet the organization's health information standards.

1.5.2.2. Data are screened for completeness, logic, and consistency.

The organization, or any contractor developing aggregate data from individual encounter reporting, must have mechanisms to assure that reported data contain all data elements required by the organization's standards. Data must be subject to logic edits to assure, for example, that reported services are consistent with the place of service or type of provider; that the number of services performed is consistent with the span of time (e.g., 20 physician hospital visits in a 2-day span of time is a potential inconsistency); or that procedures or diagnoses applicable only to enrollees of a particular age or sex are not reported for other enrollees. Finally, the integrity of data entry must be assured, through double keying or other recognized methods.

1.5.2.3. Service information is collected in standardized formats to the extent feasible and appropriate.

Standard formats are needed to assure that data elements are reported uniformly by all providers, and that reports from multiple sources are comparable and can be reliably merged into more comprehensive reports. Verification of conformity to the organization's standards should be included in the validation required under standard 1.5.3.1.

The Health Insurance Portability and Accountability Act of 1996 includes data standardization provisions that will apply to health plans and providers. Until these requirements take effect, each organization remains free to specify its own standard formats. However, because national standardization is imminent, an organization should have a plan for progressing toward commonly accepted data formats as rapidly as possible. In the interim, the use of organization-specific formats has a bearing on evaluation of the organization's compliance with other standards in this section. For example, an organization may need to validate data from contractors more carefully than it would if contractors could use the coding they routinely use in reporting to other payers. In addition, the plan may have difficulty calculating and reporting standardized performance measures that are keyed to standard coding.

1.6. Interim Standards for New Contractors. An organization that first enters into a Medicare or Medicaid contract after the date these standards are adopted by HCFA or the State Medicaid agency has a documented and well-designed strategy for achieving compliance with standards 1.3 through 1.5 and demonstrates a commitment to implementing the strategy.

See the guidelines for standard 1.1 for a discussion of the circumstances under which an organization will be reviewed using standard 1.6 .

An organization subject to this standard must develop a comprehensive and credible strategy for achieving compliance. This strategy must include year-by-year goals or

benchmarks and provide for commitment of sufficient resources to provide reasonable assurance that compliance will be achieved within the maximum permissible time frame (two years in the case of new Medicare or Medicaid contractors, or a period to be established by HCFA or the State Medicaid agency).

1.6.1. The organization develops and implements an annual work plan, approved by HCFA or the State Medicaid agency, that–

1.6.1.1. Details specific activities to achieve compliance with each of the component standards of standard 1.3 through 1.5;

The work plan for a new organization that has never operated a QAPI program will need to address every component standard. The plan for an organization whose QAPI program has been found to be deficient should focus on the identified deficiencies, and should be developed in consultation with HCFA or State reviewers.

1.6.1.2. Specifies time frames and identifies responsible parties for each activity.

The work plan must establish deadlines for completion of each step and include procedures for monitoring to assure that deadlines are met, including ongoing monitoring of any contractors to whom any activity has been delegated. A single responsible individual or organizational component must be identified for each activity, and there must be accountability to the senior official with overall responsibility for the QAPI program (see standard 1.6.3).

1.6.2. The organization has a process for formal evaluation, at a minimum annually, of the impact and effectiveness of the QAPI program strategy, and for making necessary changes.

The evaluation should assess both progress in implementing the strategy and the extent to which the strategy is in fact promoting the development of an effective QAPI program. It should consider whether activities in the organization's work plan are being completed on a timely basis or whether commitment of additional resources is necessary. The evaluation should include recommendations for needed changes in program strategy or administration. These recommendations must be forwarded to and considered by the policymaking body of the organization (see standard 1.6.3.1).

Note that this standard does not require that an organization make major revisions in its QAPI strategy each year. On the contrary, because time is needed to develop an effective program, repeated shifts in strategy would be evidence of lack of focus or adequate planning.

1.6.3. The organization's QAPI program is administered through clear and appropriate administrative arrangements, such that:

In most organizations, the QAPI program is administered by a multidisciplinary committee that includes both clinical and administrative personnel. Other arrangements are permissible, so long as the organization can demonstrate that clearly

identified individuals or organizational components are responsible for each aspect of QAPI activity and that effective organizational structures are in place to assure communication and coordination. In either case, the organization's QAPI program description must show the role, structure, staffing, and function of each participating component and the interrelations among components.

There must be evidence that the committee or other coordinating structure is effectively functioning. Meetings should be held at appropriate intervals and adequately attended. There should be evidence that issues raised are appropriately followed up in subsequent meetings or through other means, and that deliberations lead to actual directions to committee staff, other organization personnel, and/or affiliated providers.

1.6.3.1. The policymaking body oversees and is accountable for the QAPI program.

The policymaking body is defined as the governing body of the organization or a committee of senior executives that exercises general oversight over the organization's management, policies, and personnel. The policymaking body as a whole may oversee the QAPI program, or it may designate a committee to perform this function. There must be evidence that the policymaking body approves changes in the QAPI program description and approves the annual workplan. It must receive and review periodic reports on QAPI activities. The policymaking body must review the annual evaluation required under standard 1.6.2 and take action on any resulting recommendations.

1.6.3.2. A designated senior official is responsible for QAPI implementation.

There must be a single official responsible for the overall functioning of the QAPI program. This may be the organization's chief executive officer, chief medical officer or director, or another senior official who has direct authority to commit organizational resources to the QAPI effort. If the responsible official is not the chief medical officer, the organization must show, through the QAPI program description or other documentation, that the chief medical officer has substantial involvement in QAPI activities, including participation in meetings of the committee or other coordinating structure. Some organizations have a separate official who performs the functions of a medical director for mental health and substance abuse services; it is acceptable for this officer to oversee QAPI activities in these areas.

1.6.3.3. Employed or affiliated providers and consumers actively participate in the QAPI program.

All contracts with providers must require participation in QAPI activities, including provision of access to medical records and cooperation with data collection activities. If affiliated providers are not represented on the organization's QAPI committee or other core coordinating structure, there must be a clinical subcommittee or other advisory group to assure that clinicians actively participate in key activities, including: developing indicators, analyzing study results, identifying and proposing solutions to problems, and aiding in communication of QAPI activities and results to other providers.

Note that consumer involvement in establishment of QAPI program priorities is required for both new and existing contractors under standard 1.4.1.4. This standard does not create an additional requirement, but merely emphasizes that consumer input should be sought from the very outset of the organization's QAPI program planning.

1.6.3.4. There is collaboration among all aspects of the QAPI activity and other functional areas of the organization impacting the quality of clinical care and service delivery.

Interaction with the QAPI program is specifically referred to in the following standards or related guidelines:

- 2.4, Resolution of enrollee issues
- 3.3.2, Service authorization process
- 3.4.1, Development of practice guidelines
- 3.5.1.2, Recredentialing of practitioners.

2. Enrollee Rights

2.1. Policies on Enrollee Rights.

2.1.1. The organization implements written policies with respect to the enrollee rights specified in standard 2.2.

The organization must articulate enrollees' rights, promote the exercise of those rights, and assure that its staff and affiliated providers are familiar with enrollee rights and treat enrollees accordingly. While most of the standards in this domain address basic procedural protections for enrollees, they are closely related to quality of care. Interpersonal aspects of care are highly important to most patients. Enrollees' interactions with the organization and its providers can have an important bearing on their willingness and ability to understand and comply with recommended treatments, and hence on outcomes and costs.

2.1.1.1. Policies are communicated to enrollees, in the enrollee statement furnished in accordance with standard 2.3, and to the organization's staff and affiliated providers, at the time of initial employment or affiliation and annually thereafter.

Material on enrollee rights must be included in provider contracts or provider manuals and in staff handbooks or other training materials.

2.1.1.2. The organization monitors and promotes compliance with the policies by the organization's staff and affiliated providers.

The organization should monitor compliance through analysis of complaints or grievances, requests to change providers, enrollee satisfaction surveys, rapid disenrollment surveys, and other sources of enrollee input. Issues in compliance should be addressed through education or counseling of the staff or providers or other corrective action, and information on compliance with the policies should be considered during the recredentialing and staff evaluation process.

2.1.2. The organization assures that services are accessible to all enrollees, including those with limited English proficiency or reading skills, with diverse cultural and ethnic backgrounds, and with physical and mental disabilities.

[Note: the standard and guidelines in this area are undergoing legal review.]

This standard is not intended to enforce nondiscrimination requirements, although it is expected that the organization and its contractors will comply with applicable law (see standard 2.1.3). The aim of this standard is to assure that the organization's service planning takes into account the needs of its entire enrolled population and that the organization works to reduce barriers to access.

Standard 1.2.5 requires that the organization include among the focus areas for its QAPI activities issues relating to access to care and cultural competency. It is expected that an

organization's activities in this area will include identification of significant sub-populations within its enrolled population that may experience special barriers to access and continued efforts to improve accessibility of both clinical and member services for these specific groups.

In addition, the organization must develop appropriate policies and administrative systems to address access barriers likely to be encountered by individual enrollees (whether or not part of a defined sub-population). The organization is expected to assure that its facilities and those of affiliated providers are readily accessible to the physically and mentally disabled, that translator services are available as needed for non-English speaking enrollees, and that interpreter services and other accommodations (such as teletypewriter, or TTY, connections for member services) are made available to the hearing-impaired.

2.1.3. The organization assures compliance with Federal and State laws affecting the rights of enrollees.

Applicable Federal laws include, but are not limited to:

1. Title VI of the Civil Rights Act;
2. Section 504 of the Rehabilitation Act of 1973;
3. The Age Discrimination Act of 1975;
4. Titles II and III of the Americans with Disabilities Act;
5. Section 542 of the Public Health Service Act (pertaining to nondiscrimination against substance abusers); and
6. Title 45, Part 46 of the Code of Federal Regulations, pertaining to research involving human subjects.

In general, these laws are enforced by agencies other than HCFA or the State Medicaid agency, and reviews conducted under these standards will not include detailed assessment of an organization's compliance. However, HCFA or States will report any observed violations and refer any enrollee complaints to the appropriate agency for resolution.

The organization must include provisions relating to compliance with Federal and State laws in subcontracts with providers. Assessment of compliance should be included in the organization's credentialing procedures to the extent feasible and appropriate; for example, site visits to individual practitioners' offices should include a general assessment of physical accessibility.

2.2. Enrollee Rights. Each enrollee has a right—

2.2.1. to be treated with respect, dignity, and consideration for enrollee privacy;

The organization must assure that enrollees' dignity and privacy are respected in its own facilities and must address these issues in site visits to offices or facilities of affiliated primary care providers (see standard 3.5.1). Examples of privacy concerns include privacy of examining rooms and measures to assure that enrollees are not

interviewed about medical, financial, or other issues within the hearing range of other patients in ambulatory settings.

2.2.1.1. The organization implements procedures to assure the confidentiality of health and medical records and of other information about enrollees.

The organization's confidentiality procedures should apply, not just to medical records, but to any information in the possession of the organization or its contractors that could disclose medical conditions or the use of specific services, such as claims information or information collected in the course of QAPI, utilization or case management, or other processes. Standards must address both written materials and information created in other formats, such as electronic records, facsimiles, or electronic mail. The organization's procedures should protect against unauthorized or inadvertent disclosure of information to any individual, including the organization's own employees or contractors, who does not have an identifiable need for the information. In addition, they should assure that no individual retains information after putting it to use for the purpose for which it was obtained.

Review of primary care providers' own confidentiality procedures must be included as part of site visits conducted under standard 3.5.

An organization with Medicaid enrollees must have specific procedures to assure that information on enrollees' Medicaid eligibility status is released only when necessary (for example, when a provider must be able to identify Medicaid beneficiaries who are exempt from copayment requirements) and that recipients of this information in turn agree to maintain confidentiality.

2.2.1.2. The right to privacy includes the right to approve or refuse the release of identifiable personal information by the organization, except when such release is required by law.

This standard pertains to the release of information to third parties and is not meant to impede the exchange of information among the organization, its affiliated providers, and other contractors as necessary to carry out the organization's contractual responsibilities. The organization's procedures must provide that information on enrollees will be released to outside parties only with the consent of the enrollee (or authorized representative) or when required by a subpoena or other legal requirement (such as mandatory reporting of certain communicable diseases).

2.2.1.3. The organization implements specific policies with respect to confidentiality and privacy for minors, subject to applicable law.

The organization's policies must define whether and under what circumstances treatment may be furnished to a minor without parental consent and what information will be released to a parent on request. Specific issues to be addressed should include family planning, other reproductive health services, and mental health or substance

abuse services. (The review should take account of any state law requirements with respect to these issues.)

2.2.2. to choose providers from among those affiliated with the organization;

The enrollee has the right to select the affiliated provider from whom he or she will receive primary care, specialty or referral services, inpatient care, or any other covered care or service. This right is affirmative with respect to primary care; as provided under standard 2.2.2.1, each enrollee must have a right to select his or her primary care provider and to change this selection at any time. The right is negative with respect to referral or other services; that is, an enrollee may be referred to a specific practitioner or provider designated by the referring practitioner or by the organization. However, the enrollee must have the right, provided under standard 2.2.2.2, to refuse care from the designated practitioner or provider and to request referral to a different affiliated practitioner or provider. Similarly, in the case of mental health and substance abuse services, the enrollee's primary provider of these services may initially be assigned through, for example, a triage system. However, the enrollee must have a right to select a different primary provider.

In order to facilitate enrollee selection of providers, the organization must make available to enrollees, on request, information on provider qualifications and other information on providers obtained as part of the credentialing process required under standard 3.5 (other than confidential business or other information not directly relevant to an enrollee's assessment of the provider's qualifications.)

2.2.2.1. Each enrollee may select his or her primary care provider from among those accepting new Medicare or Medicaid enrollees.

New enrollees must be informed of the primary care providers available and the procedures for selecting a provider. An organization that requires use of the primary care provider to obtain other services may assign a provider for enrollees who have failed to make a selection within a reasonable time period specified in the organization's procedures. In the event of assignment, the enrollee must be notified of the assignment and of the procedures for changing the designated provider.

In the event a primary care provider ceases to be affiliated with the organization, the organization must promptly assist enrollees in obtaining a new primary care provider. The organization's procedures must provide for notice to affected enrollees at least 30 days prior to the effective date of termination of the affiliation (unless the effective date is less than 30 days after the organization knows of the termination). The notice must include information on how to select a new primary care practitioner. In the event of an affiliation terminated because a specific practitioner has left a group or facility that continues to contract with the organization, the enrollee may be offered an opportunity to select from among other practitioners at the site who are continuing to accept new patients. However, the enrollee must also be notified of the right to select another site or practitioner.

2.2.2.2. Each enrollee may refuse care from specific practitioners or providers.

An enrollee referred to a specific practitioner or provider for any service other than primary care must have an opportunity to refuse care from the designated practitioner or provider and to select a different affiliated practitioner or provider. (Medicare enrollees requesting a second surgical opinion must also be permitted to select the affiliated practitioner for this service.) To the extent feasible, this means that an enrollee must never be in the position of having only one possible source of care or services. There are two exceptions:

1. The service is highly specialized and is available from only one affiliated practitioner or provider within the service area.

2. The organization has designated a single supplier for a service that does not involve a personal encounter with a practitioner. Examples might include clinical laboratory services, medical supplies, or transportation.

This standard is not intended to require that an organization allow enrollees to use highly specialized practitioners or providers for care that can be appropriately furnished by other affiliated practitioners or providers. For example, an organization that includes a tertiary care facility among its contracting hospitals need not allow an enrollee to select that facility for a routine delivery.

Subnetworks. An organization may contract with formal subnetworks that provide a broad spectrum of care and services, or the organization may allow individual providers to establish informal subnetworks.

A formal subnetwork exists when each enrollee is required, at the time of initial selection of a primary care provider, to choose an entire subnetwork that may also include specialists, hospitals, or other practitioners or providers. For example, an organization might contract with several different integrated health systems in its service area. An enrollee selecting a primary care provider affiliated with a particular health system may be required to obtain covered services through the other providers affiliated with the system. This is permissible when:

1. Enrollee information materials clearly indicate that the organization is using a subnetwork approach and are in such form that the enrollee can readily identify the providers available through each subnetwork;
2. Enrollees are afforded a meaningful choice of providers within the subnetwork; and
3. The enrollee may change his or her choice of subnetwork at any time.

An informal subnetwork exists when an organization has delegated to a practitioner or provider the authority to refer the enrollee for services of other practitioners or providers, and the delegate limits the enrollee's choice to a subset of the practitioners or providers affiliated with the organization. For example, an organization's contract with a primary care provider may hold that provider financially responsible for specialty physician services, and the provider may in turn make financial arrangements for those

services with one or more of the specialists affiliated with the organization. The enrollee retains the right to refuse care from the specialist selected by the primary care provider and to request referral to a different specialist who is affiliated with the organization but is not a member of the practitioner's informal subnetwork. An enrollee may not be required to select a new primary care provider in order to exercise this right; this is permitted only in the case of a formal subnetwork arrangement as defined above.

2.2.3. to participate in decision-making regarding his or her health care;

The organization's policies must promote enrollees' understanding of their conditions or problems and facilitate development of mutually agreed upon treatment goals. While participation in treatment planning is important for all enrollees, special emphasis should be placed on involvement of enrollees and/or their families in development of plans of care for enrollees with mental health or substance problems.

2.2.3.1. The organization provides for the enrollee's representative to facilitate care or treatment decisions when the enrollee is unable to do so.

Written policies and procedures address the care and treatment of enrollees who are unable to exercise rational judgment or give informed consent. State law will generally govern who may act as an enrollee's representative. A representative may be (1) a person who is designated as the enrollee's representative (e.g., by a power of attorney); (2) a court appointed guardian; (3) a spouse or other family member as designated by the enrollee; or (4) another person designated by a state agency.

2.2.3.2. The organization provides for enrollee or representative involvement in decisions to withhold resuscitative services, or to forgo or withdraw life-sustaining treatment, and complies with requirements of Federal and State law with respect to advance directives.

With respect to advance directives, the organization is specifically required:

(1) to inform all Medicare and Medicaid enrollees at the time of enrollment of their right (under state law, whether statutory or recognized by the courts of the state) to accept or refuse treatment and to execute an advance directive, such as living wills or durable powers of attorney, and of the organization's written policies on implementation of that right (including a clear and precise statement of limitation, if the organization cannot implement an advance directive as a matter of conscience);
(2) to document in the enrollee's medical records whether or not an individual has executed an advance directive;
(3) to not condition treatment or otherwise discriminate on the basis of whether an individual has executed an advance directive;
(4) to comply with state law, whether statutory or recognized by the courts of the state, on advance directives; and
(5) to provide (individually or with others) for education for staff and the community on advance directives.

As a practical matter, compliance with patients' or representatives' instructions in these areas is largely in the hands of hospitals or other facilities and their attending staff. However, the organization should take at least the following steps to assure enrollees' rights:

- Include information on advance directives and other end-of-life issues in enrollee information;
- Require documentation of advance directives in medical records, verify compliance in its reviews of medical recordkeeping, and assure that primary care providers are educated about their responsibility to communicate enrollees' wishes to attending staff in hospitals or other facilities;
- Review policies of affiliated hospitals and other contracting facilities; and
- Assure that practice guidelines or guidelines used in utilization management do not impede enrollees' decision making with respect to end-of-life care.

Note that requirements related to advance directives are not limited to directives concerning care at the end of life. The organization should also assure compliance with other forms of patient instructions, such as psychiatric advance directives.

2.2.4. to receive information on available treatment options or alternative courses of care;

Contracts with providers may not limit a provider's ability to counsel or advise a Medicare or Medicaid enrollee of treatment options that may be appropriate for the enrollee's condition or disease, whether or not the options are covered by the organization. Enrollees have an affirmative right to a clear explanation of: their condition; any proposed treatments or procedures and any alternatives; the benefits, drawbacks, and likelihood of success of each option; and the possible consequences of refusal or non-compliance with a recommended course of care.

2.2.5. to have access to his or her medical records in accordance with applicable Federal and State laws; and

The organization must have procedures through which an enrollee can obtain timely access to all medical records and health information maintained by the organization, including records maintained by subcontracting providers from whom the enrollee has received services.

2.2.6. to obtain a prompt resolution, through the procedures established under standard 2.4, of issues raised by the enrollee, including complaints or grievances and issues relating to authorization, coverage, or payment of services.

2.3. Enrollee Information

Enrollee understanding of the workings of the organization, procedures for obtaining services, and rights and responsibilities, are essential to the provision of quality care. This standard measures the comprehensiveness of the content of enrollee information and the accessibility of this information. Review of compliance with this standard is

part of a broader review of the organization's basic information for enrollees. This standard addresses only those elements of enrollee information that are directly related to the use of health services. (Guidelines are provided below only for those individual elements that are not self-explanatory.) Note that information required to be furnished to enrollees must also be made available to any representative designated by or on behalf of the enrollee.

2.3.1. Each enrollee receives, at the time of enrollment and at least annually thereafter, a written statement including information on:

2.3.1.1. Enrollee rights;

2.3.1.2. Enrollee responsibilities, including the responsibility to provide information needed for treatment, to follow the organization's procedures for obtaining services, and to follow instructions and guidelines given by those providing services;

While it is advisable to include a discussion of enrollee responsibilities in enrollee information, the discussion should clearly indicate that enrollment is not conditional on the enrollee's agreement to follow a particular course of prescribed treatment.

2.3.1.3. The names and locations of network providers, including information on which providers are accepting new Medicare or Medicaid patients and any restrictions on enrollees' ability to select from among network providers;

Enrollees making a decision about whether to enroll in a particular organization may rely on the organization's provider listings in making their selection and may assume that (subject to the organization's authorization procedures) they will be able to obtain covered services from any of the providers listed. It is essential that the organization's informational materials emphasize any limitations on enrollees' provider selections. If the organization contracts with formal subnetworks (see standard 2.2.2.2) and requires enrollees selecting a particular subnetwork for primary care to use that subnetwork's affiliated providers for referral services, informational materials must clearly indicate which individual practitioners or providers are available under each subnetwork (for example, through a simple coding system or separate provider listings for each subnetwork). If the organization's arrangements with primary care providers allow for the establishment of informal subnetworks, informational materials must so indicate and must explain the procedures under which an enrollee may request referral to an affiliated provider not included in the informal subnetwork.

2.3.1.4. Benefits and services included and excluded as a condition of enrollment, including a description of how the organization evaluates new technology for inclusion as a covered benefit;

It is not expected that standard enrollee information will include every specific coverage decision made by the organization, such as a listing of its entire drug formulary or its criteria for approval of specific medical procedures. However, materials must indicate how an enrollee may obtain this information.

2.3.1.5. Procedures for obtaining services, including authorization requirements, any special procedures for obtaining mental health and substance abuse services, procedures for obtaining out-of-area coverage and, in the case of enrollees eligible for a point-of-service benefit, procedures for obtaining services through the benefit, including special conditions or charges that may apply;
2.3.1.6. In the case of Medicaid enrollees, procedures for obtaining services covered under the Medicaid state plan and not covered by the organization, and notice of the right to obtain family planning services from any Medicaid-participating provider (unless otherwise restricted);
2.3.1.7. Provisions for after-hours and emergency coverage, including the organization's policy on when enrollees should seek direct access to emergency care;
2.3.1.8. Policies on referrals for specialty care and other services not furnished by the enrollee's primary care provider;
2.3.1.9. Charges to enrollees, if applicable;
2.3.1.10. Procedures established under standard 2.4 for resolving enrollee issues, including complaints or grievances and issues relating to authorization of, coverage of, or payment for services;
2.3.1.11. Procedures for changing primary care providers;
2.3.1.12. Procedures for recommending changes in policies or services; and
2.3.1.13. Notice of the right to obtain information on physician incentive plans and results of required surveys.

2.3.2. The organization notifies enrollees affected by termination of or changes in benefits, services, service sites, or affiliated providers.

Notice of changes in benefits or in the organization's rules for obtaining benefits must be provided to affected beneficiaries at least 30 days before the change takes effect. Whenever feasible, 30 days notice should be provided for any other changes. Changes affecting enrollees generally should be communicated through bulletins, newsletters, or other plan-wide documents. Notice of the termination or withdrawal of specific providers may be furnished only to the enrollees using those providers; when the provider is a primary care provider, the notice should include a reminder on the procedures for changing providers.

2.3.3. Enrollee information is–
2.3.3.1. readable and easily understood;

Generally materials should be understandable to enrollees at a fifth-grade reading level (or another level established by the State Medicaid agency). Materials should use an easily readable typeface and frequent headings, and should provide short, simple explanations of key concepts. Technical or legal language should be avoided whenever possible.

2.3.3.2. available in the language(s) of the major population groups served and, as needed, in alternative formats for the visually impaired.

The organization must have a procedure for ascertaining the primary language of enrollees and for making information materials available in any language that is the primary language of more than 10 percent of enrollees.[1] Basic enrollee information, except for the provider listing required under standard 2.3.1.3, must also be made available to the visually impaired in large print and Braille formats or through recorded cassettes.

2.3.4. The organization assesses and improves the effectiveness of its communications with enrollees through consumer testing, surveys, or other means.

The organization's enrollee surveys should include a focus on the extent to which enrollees understand key concepts of health plan enrollment and are able to use information materials. If possible, materials should be tested with focus groups or enrollee advisory committees.

2.4. Resolution of Enrollee Issues. The organization has a system for resolving issues raised by enrollees, including complaints or grievances; issues relating to authorization of, coverage of, or payment for services; and, in the case of Medicare enrollees, issues relating to discontinuation of a service. [NOTE: references to an enrollee in these standards include reference to an enrollee's representative.]

[NOTE: The draft standard and guidelines generally use Medicare terminology for different types of issues and issue resolution processes. It is recognized that there is a potential for confusion, because State Medicaid agencies may currently use different terminology for the same functions. If possible, neutral terms will be identified that can be applied both to Medicare and Medicaid processes.]

Medicare and State Medicaid programs use a variety of terms for circumstances in which an enrollee voices a concern with, or requests an action by, the organization. Different processes, both for the organization and for HCFA or the State Medicaid agency, govern the resolution of different types of issues raised by enrollees. This standard presents a unified structure for evaluating the organization's performance in carrying out those elements of each process for which it is responsible.

The standard distinguishes among three basic categories of enrollee issues:

1. Initial requests that the organization or its subcontractor provide or authorize a service or pay for a service already obtained.

This category includes requests made directly to a provider, requests made by an enrollee or a provider through an organization's system for prior approval of services,

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[1] This threshold, based on that established in some state Medicaid contracts, is necessarily arbitrary. However, some numeric threshold must be established if this standard is to be enforceable.

and requests in the form of claims for payment filed by the enrollee or a provider. Any such request results in an initial decision by the organization (or by a provider to whom the initial decision-making authority has been delegated) to approve or disapprove provision of or payment for the service. (Under Medicare, this decision is known as an "initial determination.")

Standard 3.3, on service authorizations, sets forth some basic rules for initial consideration by the organization or its delegate of service or payment requests that are considered through the organization's prior authorization system or claims processing system (or comparable systems operated by subcontractors). As explained under standard 3.3, those rules do not apply when an enrollee requests a service directly from a provider and the provider decides whether or not to furnish or arrange the service without referring the request to anyone else. For example, an enrollee may ask his or her primary care physician to make a referral for a given surgical procedure. If the physician agrees to make the referral and then seeks approval through the organization's authorization system, a decision (or "initial determination") has not been made until the organization's authorization system has approved or denied the request. If, on the other hand, the physician determines that a referral is inappropriate and declines to seek authorization, the physician has already made an initial decision and must explain to the enrollee how to obtain a reconsideration of that decision under standard 2.4.3. The same would be true if the physician declined to perform a requested service that the physician could furnish on his or her own.

2. Requests that the organization, its subcontractor, or a government agency reconsider a decision not to provide or authorize a service or pay for a service already obtained.

When an organization or its subcontractor makes an initial decision not to provide or pay for a covered service (or a service that is perceived by the enrollee as covered), the enrollee is entitled to a reconsideration. This is true both of determinations that a requested service is not covered under the Medicare or Medicaid contract and of decisions that a covered service is not necessary or appropriate for the particular enrollee.

Under Medicare, a request for reconsideration is initially reviewed by the organization. If the organization does not make a "fully favorable" determination--that is, agree to provide or pay for the service--the request is forwarded to the "reconsideration contractor," an entity under contract to HCFA to resolve coverage disputes, and may be subject to further levels of administrative or judicial review. This process applies both for basic services (services covered under the Medicare statute for all beneficiaries) and for "mandatory" supplemental services (services covered under a package that all Medicare enrollees must purchase as a condition of enrolling in the organization under its Medicare contract). Standard 2.4.3 addresses the process of reconsideration by the organization itself and does not address the subsequent steps in the process.

The Medicare reconsideration process, including external review of reconsideration requests, does not apply to requests related to "optional" supplemental services (non-Medicare services covered under a supplemental benefit package that each Medicare

enrollee may choose whether or not to purchase). Disputes related to optional supplemental services are resolved solely through the organization's internal grievance process.[2] [The following is under review by HCFA.] In addition, reconsideration applies only to a request for a specific service that the enrollee perceives or contends is actually covered under the contract. A general complaint that, for example, an organization has failed to include outpatient prescription drugs in its supplemental benefit package is not a request for a service.

Under Medicaid, an enrollee has an immediate right to appeal the organization's initial decision to the State agency, through the fair hearing process established by the State agency under 42 CFR 431.200. The agency may encourage the enrollee to make an initial attempt to resolve the issue through the organization's own reconsideration process, but may not require the individual to do so before filing an appeal with the State. Standard 2.4.3 thus applies only to instances in which the enrollee agrees to request reconsideration from the organization.

3. Complaints or grievances on all other matters.

Enrollee concerns on all issues not involving a request for provision of or payment for a service are treated as grievances and are subject to the procedures established under standard 2.4.2. This standard does not distinguish between "formal" and "informal" grievances, or between "grievances" and "complaints." For the purpose of these standards a grievance is defined as:

> Any communication, oral or written, from an enrollee to any employee of the organization or of its providers, expressing dissatisfaction with any aspect of the organization's or provider's operations, activities, or behavior, regardless of whether any remedial action is requested.

Examples of possible subjects of grievances include, but are not limited to, complaints about:

- The quality of services provided (other than a refusal to furnish a requested service);
- Interpersonal aspects of care, such as rudeness by a provider or staff member;
- Failure to respect any of the enrollee's rights, as set forth in standard 2.2.

Under both Medicare and Medicaid, certain issues relating to disenrollment of an enrollee may also be considered through the organization's grievance process. Medicare requires that an organization seeking the involuntary disenrollment of an enrollee for cause must allow the enrollee to contest the organization's decision through the grievance process.

If the Medicaid agreement with an organization provides for "lock-in" – a fixed period[3] during which an enrollee may disenroll only for "good cause" – enrollee requests for

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[2] Note, however, that a dispute over whether a particular service is properly considered basic, mandatory supplemental, or optional supplemental, is subject to review by the reconsideration contractor.

[3] Generally 6 months, or 12 months in certain states with section 1115 demonstration waivers.

disenrollment for cause may at the State's option be initially processed through the organization's grievance procedure. In this case, the time frames specified in the organization's procedures must be such as to comply with the requirement that disenrollments for cause take effect no later than the first day of the second month following the month during which the enrollee requested disenrollment.

2.4.1. Intake of Enrollee Issues. The organization follows written procedures for the receipt and initial processing of all issues raised by enrollees. The organization–

The organization has received an issue when the enrollee directs any oral or written communication about the issue to any employee of the organization or its contracting providers, or when an enrollee concern is forwarded to the organization by another entity (for example, when a Social Security or Railroad Retirement office transmits a complaint made by a Medicare beneficiary). It is therefore essential that all personnel who may come into contact with enrollees understand the basic procedures for receiving and recording an issue and for initiating the applicable process for resolving the issue.

2.4.1.1 documents each issue raised by an enrollee;

When an enrollee raises an issue, the enrollee must immediately be informed of whether the issue is (a) one that the enrollee must present to the organization in writing or (b) one that the enrollee may present orally and that will be recorded by the person receiving the issue. Requests for a service or payment, or for reconsideration of an initial decision to deny a service or payment request, must be presented by the enrollee in writing. However, in the case of Medicare's expedited reviews, oral requests are permitted. Grievances may be presented orally, although the enrollee must always be notified that he or she has the right to present a written grievance. If the person receiving the issue is uncertain of what category it falls into, the issue must be presented by the enrollee in writing.

There may be instances in which an enrollee expresses a concern orally to staff of the organization or an affiliated provider, and the issue is resol··d to the enrollee's satisfaction immediately and informally. Nevertheless, the issue and its resolution must be recorded, through a complaint log or other means, so that information on volume and nature of enrollee issues is available in the QAPI process and for other management functions.

2.4.1.2. promptly determines whether the issue is to be resolved through: (a) the grievance process established under standard 2.4.2, (b) the process for making initial determinations on coverage and payment issues established under standard 3.3, or (c) the process for resolution of disputed initial determinations established under standard 2.4.3;

Except in the case of grievances that are immediately resolved to the enrollee's satisfaction, the person receiving the enrollee issue must determine what type of issue it

is and how it will be resolved (or must promptly forward the issue to personnel authorized to make this determination).

2.4.1.3. acknowledges receipt of the issue and explains to the enrollee the process to be followed in resolving his or her issue;

As soon as the organization has made the determination required under standard 2.4.1.2, the enrollee must receive an acknowledgment that the issue has been recorded and a clear explanation of how it will be resolved, describing each step in the process, the time frame for each step, and the enrollee's rights or responsibilities at each step. In the case of grievances, acknowledgment of receipt and explanation of the process may be made orally; however, grievances relating to quality of care issues must be acknowledged in writing, and the acknowledgment must specifically describe the issue raised by the enrollee.

2.4.1.4. assists the enrollee as needed in completing forms or taking other necessary steps to obtain resolution of the issue; and

2.4.1.5. informs the enrollee of any applicable mechanism for resolving the issue external to the organization's own processes.

The enrollee must be notified of alternative routes for resolution of his or her issue. Under Medicare, for example, an enrollee has a right to submit a quality of care complaint for investigation by the PRO, instead of pursuing it through the organization's grievance process. Under Medicaid, coverage and payment issues may be presented to the State agency at any time, even if the organization is already reviewing the issue through its reconsideration procedure. In addition, some States may have issue resolution mechanisms that are available to commercial enrollees of organizations as well as to Medicare and Medicaid enrollees, such as a hotline or other complaints system maintained by the Insurance Commissioner or another State agency. (Such a system would supplement, but not replace, the State Medicaid agency's own hearing process.)

2.4.2. Grievances. The organization implements a procedure, with clearly explained steps and time limits for each step, for the resolution of a complaint or grievance.

2.4.2.1. The grievance is transmitted in a timely manner to staff who have authority to take corrective action. A grievance relating to quality of care is transmitted to appropriately qualified clinical personnel.

2.4.2.2. The organization investigates the grievance and notifies the concerned parties of the results of the investigation and the proposed resolution.

The resolution must directly address the issue raised in the grievance, and the proposed solution must be appropriate to the seriousness of the complaint.

2.4.2.3. The organization provides an opportunity for reconsideration of the proposed resolution.

When the enrollee is not satisfied with the proposed resolution of a grievance, there must be an opportunity for further consideration by an individual or individuals other than the individual who initially reviewed the grievance. At some stage in the grievance process, the enrollee or enrollee's representative must have an opportunity to appear in person before a panel or other review body, the majority of whose members have not previously been involved in reviewing the grievance.

2.4.2.4. The organization tracks each grievance until its final resolution.

The organization must have a system for monitoring its progress in reviewing and resolving each grievance, to assure that each step is completed within the time frame specified in the organization's grievance procedures.

2.4.2.5. The organization has an expedited grievance process for issues requiring immediate resolution.

Standard 3.3 provides for expedited consideration of urgent requests for service. Under both Medicare and Medicaid, however, there may be issues that are treated as grievances and are therefore not subject to this process, but that may nevertheless require rapid response. This would be true, for example, when an enrollee reports that he or she is unable to obtain a timely appointment from a primary care provider for a problem in need of immediate attention or when the organization has denied authorization for a supplemental service that the enrollee believes is urgently needed and that is not subject to the Medicare reconsideration process. Thus an expedited grievance process is required in all organizations, regardless of the applicable procedure for obtaining reconsideration of denials of service.

2.4.3. Reconsideration of Coverage and Payment Determinations. The organization implements a procedure, with clearly explained steps and time limits for each step, for reviewing requests for reconsideration of initial decisions not to provide or pay for a service.

As noted earlier, this standard applies to Medicare reconsiderations related to basic or mandatory supplemental services, and to Medicaid reconsiderations only when the enrollee agrees to pursue the issue through the organization's internal process.

2.4.3.1. The organization's notice to an enrollee and/or provider of its decision to deny, limit, or discontinue authorization of, or payment for, a service includes information required under standard 3.3.1.5, including information about how to obtain a reconsideration of the decision. The notice to the enrollee must be in writing.

When a service request is made directly to a provider and the provider denies the request orally, the provider must immediately notify the enrollee of the right to obtain reconsideration and the procedure for requesting reconsideration.

2.4.3.2. The organization's process complies with procedural requirements and time limits established by HCFA or the State Medicaid agency.

Medicare regulations specify procedures time limits for service determinations. Each State may establish its own requirements for Medicaid.

2.4.3.3. Requests for reconsideration by the organization of a denial based on lack of medical necessity are reviewed by an individual with appropriate clinical expertise who is not the individual who made the initial determination.

If the organization delegates any phase of the reconsideration process to a subcontractor, the subcontractor must have its own procedures for complying with this standard. This standard means that the reconsideration function may not be delegated to a solo practitioner.

2.4.4. Monitoring of Issue Resolution Processes. The organization maintains, aggregates and analyzes information on the nature of issues raised by enrollees and on their resolution.

2.4.4.1 The information is used to develop activities under the organization's QAPI program, both to improve the issue resolution process itself and to make improvements that address other system issues raised in the process.

See standards 1.2.5.1 and 1.2.5.2.

2.4.4.2. Information related to coverage and payment issues is maintained for at least three years following final resolution of the issue, and is made available to the enrollee on request.

Self-explanatory.

3. Health Services Management

3.1. Availability and Accessibility. The organization assures that all covered services, including additional or supplemental services contracted for by or on behalf of Medicare or Medicaid enrollees are available and accessible.

The organization must assure that all services are available: that is, that it has employed or contracted with appropriately qualified practitioners and providers, and that these practitioners and providers have sufficient capacity to make services available to the organization's enrollees. The organization must also assure accessibility: that is, that enrollees can obtain available services in a timely fashion, taking into account travel and waiting times and potential access barriers for special populations, such as the disabled or non-English speaking enrollees (see standard 2.1.2).

An organization newly contracting with Medicare or Medicaid, or requesting an expansion of its approved service area, meets this standard by demonstrating in advance, pursuant to standard 3.1.1.1, that its network is adequate to meet projected population needs. An established contractor meets this standard by developing a process, pursuant to standard 3.1.1.2, for continuous assessment and improvement of availability and access. An established organization is thus not required to repeat the basic demonstration of network adequacy required for a new or expansion application. However, a formal re-assessment of network adequacy may be required if there is a significant change in the organization's network or in the size or composition of its enrolled population, or if there is evidence of continuing accessibility problems not resolved through the QAPI process.

Both new and established contractors must meet basic structural requirements, including assuring that (with minor exceptions specified below) all services are provided through written subcontracts that meet Federal and State standards, and verifying that all providers are appropriately qualified.

> **3.1.1. The organization maintains and monitors a network of providers, supported by written arrangements, that is sufficient to provide timely access to covered services.**

The organization's network consists of employees and facilities of the organization, if any, along with practitioners and providers who have entered into written agreements to serve the organization's enrollees. Agreements must conform to applicable requirements of these standards and to other Medicare and Medicaid requirements for subcontracts. (If the organization's subcontracts with providers allow those providers to enter into sub-subcontracts with other providers for services to Medicare or Medicaid enrollees, those sub-subcontracts must also meet applicable standards.)

Services (other than in-area emergency care and out-of-area emergency and urgent care) must generally be available within the organization's network. Network practitioners and providers must be located within the organization's approved service area, except that an organization operating solely in a non-metropolitan area may make a service

(other than primary care and emergency care) available outside the area if it is unable to contract with a sufficient number of providers within the area.

An infrequently used service may be made available through practitioners and providers who have not entered into a formal written agreement with the organization. An infrequently used service is one that: (a) in the case of medical specialties, accounts for less than one percent of the organization's enrollee physician encounters, or requires less than 0.25 full-time equivalent physicians; (b) for other services, accounts for less than one percent of the organization's total medical care costs. The organization should assess when utilization or cost exceeds these thresholds and establish in-network arrangements as necessary. If any service is to be furnished through non-contracting providers, the organization must have procedures for identifying appropriate providers, referring enrollees to the providers as needed, and assuring that the providers will accept payment from the organization as payment in full (subject to any allowable copayments or other cost-sharing).

An organization that offers a point-of-service benefit must still make all services available within its network (or through arrangements with non-contracting providers as described above). No enrollee may be required to use the point-of-service benefit, or pay any extra charges imposed under that benefit, in order to obtain any medically necessary covered service.

3.1.1.1. A new contractor, or an established contractor seeking an expansion of its service area, demonstrates that the numbers and types of providers available to enrollees are sufficient to meet anticipated needs of the population and area to be served.

Because enrollee needs, the types of practitioners and providers used by an organization to meet those needs, and other factors such as availability of public transportation will vary for each organization, it is impossible to develop a single set of fixed guidelines for all populations and all circumstances, such as prescribed primary physician/enrollee ratios or specified waiting times for appointments of different kinds.

HCFA or State Medicaid agencies may establish such standards for contractors serving specific populations or areas; for example, a State might include specific guidelines in a request for proposals. Or standards may be developed in the course of the general contract negotiation process. Ultimately, however, it is the organization that must assess the needs of the population it proposes to enroll and structure a network to meet those needs. Review of compliance with this standard will therefore generally focus on the organization's own service planning and on the basic assumptions used by the organization itself in determining that its network is ready to serve Medicare or Medicaid beneficiaries in a given area.

It is expected that each organization seeking a new contract or expanded service area will—

- develop availability and accessibility standards appropriate to its circumstances,

- document the basis for these standards, and
- demonstrate that its initial network capacity is sufficient to meet the standards.

In addition, an organization that plans to furnish services through multiple formal subnetworks, as defined in the guidelines for standard 2.2.2, must assure that each subnetwork has adequate capacity to meet anticipated needs of the population it is projected to serve.

The organization's initial assessment of availability must consider, for each type of covered service and for major specialties within each type:

- Expected utilization of services, taking into account enrollee characteristics and health care needs.

The aggregate number of providers needed, and their distribution among different specialties, will vary according to the organization's projected population (in terms of age, disability, prevalence of certain conditions). It may also be affected by practice patterns within the organization, such as the rate of referrals for specific services. New organizations may initially base their standards on regional or national data from comparable organizations. Established organizations entering a new service area may instead use their own utilization data.

- The numbers and types of providers needed to furnish these services.

Assessment of the numbers of providers needed to meet an expected level of demand for services can again be based on national norms (such as typic ' physician/patient ratios) or on an organization's past experience. However, simple counts of providers, or even providers reportedly accepting new patients, are insufficient to establish capacity. Except when practitioners or providers serve the organization's enrollees exclusively, assessment of capacity necessarily entails assessment of the volume of services being furnished to patients other than the organization's enrollees. The organization must therefore have a process for measuring available full-time equivalents (in the case of individual practitioners) or unused capacity (in the case of hospitals or other facilities).

Where more than one type of practitioner is qualified to furnish a particular item or service, the organization's standards must define the types of practitioners to be used. For example, although under fee-for-service Medicare a chiropractor may provide manual manipulation of the spine to treat a subluxation, the organization may instead provide this service through a physician or physical therapist. (Some states may have laws requiring health plans to make specific types of practitioners available.) The organization's standards should specifically define the types of mental health and substance abuse practitioners to be included (e.g., psychiatrists, psychologists, clinical social workers, psychiatric nurses). In addition, the organization must specify the types of practitioners who may serve as an enrollee's primary care practitioner (see standard 3.2.1.2).

Medicare does not require that any specific physician service be furnished by board-certified specialists. However, an organization is expected to make specialists available to enrollees for services customarily furnished by specialists in the organization's service area. (Note that Medicaid rules specifying who may furnish services to pregnant women and children were repealed by the Balanced Budget Act of 1997.)

- Geographic location of providers and enrollees.

The organization must assure that providers are so distributed that no enrollee residing in the service area must travel an unreasonable distance to obtain any covered service. As a general rule, primary care services and commonly used specialty and referral services must be available within 30 minutes driving time from any point in the service area. Longer travel times for a particular service are permissible when residents in part or all of the service area customarily travel greater distances to obtain that service (e.g., in rural areas, or when there is only provider of a given type in a broad region.) Organizations with significant numbers of Medicare or Medicaid enrollees must consider, not just driving time, but the usual means of transportation used by those enrollees. In areas where elderly, disabled, or low-income residents rely heavily on public transportation, the organization must assure that providers are accessible through these means. (Unless, as under some Medicaid arrangements, the state or the organization makes alternative transportation available, or unless the organization assures access through alternative means, such as home visits.)

3.1.1.2. An established contractor establishes standards for timeliness of access to care and member services that meet or exceed such standards as may be established by HCFA or the State Medicaid agency, continuously monitors the extent to which it meets these standards, and takes corrective action as necessary.

An established organization assures access and availability of services by developing its own standards and continuously monitoring its own compliance with these standards. HCFA or State Medicaid agencies may promulgate, or include in contracts, specific access standards to be met by the organization, in which case the organization's monitoring activities must be conducted in light of those standards. Note that, in an organization that serves both commercial and Medicare or Medicaid members, and whose commercial, Medicare, and Medicaid networks are not identical, assessment of compliance with availability and accessibility standards must be performed separately for the Medicare and Medicaid populations.

Access issues relating to particular services or population needs may be addressed as a part of the QAPI process, through projects in focus areas 1.2.5.4, 1.2.5.5, and 1.2.5.6. However, it is also expected that the organization will, as a routine administrative function, continuously assess access to all types of services and modify its network arrangements as necessary to correct any observed deficiency.

Standards. The organization must establish standards of timeliness of appointments and in-office waiting times for each type of service. The standards should consider the

immediacy of member needs and common waiting times for comparable services in the community. An example of reasonable standards for primary care services might be:

- Urgent but non-emergent - within 24 hours
- Non-urgent but in need of attention - within one week
- Routine and preventive - within 20 days

Standards should include criteria for classification of complaints by level of urgency.

The organization must assure that affiliated practitioners and providers are aware of the standards and have mechanisms in place for complying. For primary care practitioners, the organization should obtain documentation of backup arrangements for vacations and other absences, and assure that backup practitioners are familiarized with plan procedures, such as approval requirements for referral services.

The organization must also have standards for responsiveness of member services telephone lines. The standards should specify maximum average waiting times to reach a non-recorded voice. In an organization with substantial low-income membership, these standards should take into account the likelihood that such members may not have access to touch-tone systems and may be using telephones outside their residences.

Monitoring. The organization must continuously monitor compliance with its own standards for timely access to services. Tools for monitoring might include:

- Member surveys.
- Analysis of member complaints and grievances.
- Practitioner and provider self-reports of appointment and in-office waiting times, supplemented by random calls or audits.
- For the organization's own services, test calls and ongoing monitoring of telephone abandonment rates (the percentage of callers who terminate a call before reaching an organization representative).

Note that the organization's work in this area must evaluate access and availability for all services, not merely primary care. Thus the organization may not, for example, base its monitoring solely on general surveys of its enrolled population that do not yield information on availability of specialty or other services or do not provide a sufficient sample of enrollees requiring such services. (One possible source of this information would be reports by primary care practitioners of difficulties in arranging necessary referral services.)

Corrective action. The organization must initiate corrective action when services are found not to be available within the time frames specified by its accessibility standards. When the problem applies to an entire service type or specialty, this may involve expanding the organization's facilities or provider network. When the problem involves a specific practitioner or provider, possible actions might include closing off the provider to new members or monitoring to assure that the provider is treating the

organization's members in the same way as non-members. The organization's procedures must include processes for assessing the effectiveness of corrective action.

3.1.2. All providers are determined to be qualified through the process established under standard 3.5.

Note that, if the organization's subcontracts with providers allow those providers to enter into sub-subcontracts with other providers for services to Medicare or Medicaid enrollees, either the organization or its subcontractor must determine, pursuant to standard 3.5, that each sub-subcontractor is appropriately qualified and is not excluded from participation in Medicare or Medicaid.

3.1.3. When medically necessary, the organization makes services available 24 hours a day, 7 days a week.

NOTE: This requirement is distinct from the requirement that the organization pay non-network providers for emergency services and urgent out-of-area services; these payment requirements are enforced in reviews of the organization's claims processing function and are not addressed in these standards. Instead, standard 3.1.4 restates a requirement of Medicare law and Medicaid regulations that the organization itself must make services available at all times. Although this requirement has been in effect for some years, existing review guidelines have never formally defined precisely what sort of all-hours capacity the organization is expected to maintain. Must there be specific facilities available to furnish urgent care to the organization's enrollees? To what extent may the organization rely on the back-up arrangements of its affiliated providers? Is it sufficient for the organization to operate a 24-hour telephone advice line? If so, what level of professional should be available through this service? HCFA would welcome comments on these issues from reviewers of these draft guidelines.

3.2. Continuity of Care. The organization promotes continuity of care and integration of services through:

3.2.1. Use of a health care professional who is formally designated as having primary responsibility for coordinating the enrollee's overall health care;

Traditionally, many health maintenance organizations and similar entities have used a "gatekeeper" model, under which the enrollee's usual source of primary care served as the entry point for all other medical care services (often a distinct entry point was established for mental health and substance abuse services). While this model is still quite common, some organizations have systems under which a health professional other than the enrollee's usual source of primary care, such as a case manager, coordinates services. In other organizations, enrollees may be free to obtain services from any network provider without authorization. The enrollee may have no usual source of primary care, and the organization may or may not have mechanisms in place for assuring coordination and continuity.

These standards reflect the diversity of organizational structures by distinguishing among three different activities:

Delivery of primary care. Whether or not the organization uses a gatekeeper model, establishment of an ongoing relationship with a usual source of primary care plays an important role in promoting continuity and quality of care. The organization is therefore required to make every effort to promote such a relationship, even in arrangements that allow direct access to providers other than the primary care provider.

Coordination of services. A single health care professional, who may or may not be the enrollee's primary care provider, must have primary responsibility for evaluating the enrollee's needs, recommending and arranging the services required by the enrollee, and facilitating communication and information exchange among the different providers treating the enrollee.

Authorization of services. Many organizations have what amounts to a two-step process for determining whether non-urgent, non-primary care services will be provided or paid for: (a) the service must be recommended by the primary care provider or service coordinator, and (b) the service must be approved through a utilization management system. However, Medicare and Medicaid enrollees have a right to request any covered service, whether or not the service has been recommended by the health professional responsible for coordinating their care. It is therefore important to distinguish between the coordination function described in this standard and the approval function described in standard 3.3, even if a single health professional may sometimes play a role in both functions.

3.2.1.1. The organization's policies specify whether services are coordinated by the enrollee's primary care provider or through some other means;

An organization may establish different mechanisms for different types of enrollees. For example, care of most enrollees might be coordinated by the primary care provider, while a case manager coordinates care of enrollees with complex needs, chronic illnesses, or functional disabilities.

An organization may provide for separate coordination of medical services and of mental health and substance abuse services, so long as the organization has procedures to assure the exchange of necessary information between medical care providers and mental health and substance abuse providers, for example with respect to prescribed medications. If the practitioner to whom an enrollee is referred for mental health or substance abuse services is not a physician, the organization must have procedures to assure that the enrollee has timely access to a physician for medication evaluation and management, and for evaluation of comorbidity.

3.2.1.2. Regardless of the mechanism adopted for coordination of services, the organization assures that each enrollee has an ongoing source of primary care.

The organization's policies must specify who may serve as the primary care provider for an enrollee.

Use of specialists. Although primary care is ordinarily furnished by general practitioners, family practitioners, pediatricians, internists, and sometimes obstetricians/gynecologists, it may be appropriate for some enrollees to obtain routine care from another specialist. There is some evidence that the overall care of patients with certain chronic medical conditions is most effectively managed by physicians outside the traditional primary care specialties (such as a geriatrician, an oncologist, a cardiologist, or an endocrinologist). Similarly, there may be enrollees for whom a psychiatrist coordinates medical as well as mental health or substance abuse services. The organization must have procedures for evaluating a request by an enrollee (or by a practitioner on the enrollee's behalf) to use a non-primary care specialist as his or her principal source of care.

Use of non-physician practitioners. An organization may permit licensed practitioners other than physicians to serve as primary care practitioners with appropriate supervision. (Qualifications of such practitioners, and the degree of supervision required, are generally established under State law). If an organization designates non-physician practitioners as primary care providers, it must still assure that each enrollee has a right to direct access to a physician for primary medical care. This right may be assured in either of two ways: (a) the enrollee may choose between a physician and non-physician primary care practitioner, and may change this choice at any time; or (b) when the enrollee is not allowed such a choice, an enrollee with a non-physician primary care practitioner may have timely access to a physician upon request. For example, an organization might adopt a team approach, under which all enrollees seeking primary care are initially evaluated by a nurse practitioner or other qualified non-physician working under the supervision of one or more physicians. However, the enrollee must always have an opportunity to request a follow-up appointment with a physician, and the enrollee's ability to do so may not be subject to the discretion of the non-physician practitioner.

Designation of an entity as primary care provider. An organization may allow an enrollee to select a physician group, clinic, federally qualified health center, or other facility with multiple practitioners as his or her primary source of care. To the extent feasible, the enrollee must be allowed to choose an individual primary care practitioner within the group or facility. In addition, the organization must confirm that the group or facility's medical recordkeeping practices are such as to assure that necessary information is available to each practitioner furnishing primary care to the enrollee. (See standard 3.6.)

3.2.2. Programs for coordination of care, including:

3.2.2.1. Identification of enrollees with complex needs and development of services and programs to assist them in meeting those needs;

In addition to its general care coordination mechanism established under standard 3.2.1.1, the organization should have care coordination programs to facilitate communication and information exchange among professionals involved in the care of conditions that require multiple sources of treatment or levels of care. This standard does not require that an organization develop formal programs for every variety of

complex problem. Instead, the expectation is that the organization will identify conditions that are prevalent in its population and for which continuity and effectiveness of care would be improved through targeted programs. Effective programs should set individual treatment goals for each participant, identify necessary resources, and periodically evaluate outcomes and the need for further intervention.

3.2.2.2. Coordination of medical care, mental health services and substance abuse services, and social services and community resources;

An organization with enrollees with mental illness, substance abuse problems, developmental disabilities, functional disabilities, or complex problems involving multiple medical and social needs (e.g., HIV/AIDS) should have a program or policies for assuring coordination among medical, mental health, and substance abuse services, and available social services or other community supports. The organization must have a procedure under which primary medical care, mental health, or substance abuse providers may refer an enrollee for multidisciplinary assessment and development of a plan for coordination of medical and social services. The organization's standards should define the types of enrollees who are candidates (including a definition of functional disability) and specify the types of practitioners or disciplines to be included in the assessment team.

As noted under standard 3.2.1.1, the organization must also have general procedures to assure exchange of information among medical care and mental health and substance abuse providers. (States that have separately contracted with organizations to provide mental health and substance abuse services will need to develop systems for coordination between these organizations and those providing medical care.) In addition, the organization must have training programs for primary care providers, or assure that they receive training, to familiarize them with common mental health and substance abuse problems and to assure that they can identify enrollees in need of referral for these services.

An organization with Medicaid enrollees must also assure coordination with the Special Supplemental Food Program for Women, Infants, and Children (WIC); this includes assuring that the organization's providers refer potentially eligible enrollees to the program.

3.2.3. Procedures for timely communication of clinical information among providers, as specified in standard 3.6;3.2.4. Measures to assure that enrollees are informed of specific health care needs that require follow-up and receive, as appropriate, training in self-care and other measures enrollees may take to promote their own health; and

The organization should assure that enrollees receive the information they need to participate fully in their own care, including information on such subjects as self-care, medication management and the use of medical equipment, potential complications and when these should be reported to practitioners, and scheduling of follow-up services. For example, the organization's procedures should provide for patient education as part of its discharge planning process.

3.2.5. Systems to address barriers to enrollee compliance with prescribed treatments or regimens.

The organization should make counseling and facilitating services available, on referral from providers or staff, for enrollees who are unable to, or are failing to, cooperate in their own treatment. Counseling services should include identification of social, financial, or other barriers that are preventing enrollees from following guidance or instructions from providers, with referral to appropriate social services as necessary.

3.3. Service Authorization

As was discussed under standard 2.4, the following standards apply to an organization's initial decision or determination in response to a request by an enrollee (or by a provider on behalf of the enrollee) for coverage of a service or continuation of a service previously approved.

These standards do not apply when an enrollee requests a service directly from a provider and the provider is authorized by the organization to decide whether or not to furnish or arrange the service without referring the request to anyone else. Principles for determining when such a provider is making an initial decision or determination are discussed under standard 2.4. These standards do apply when an individual practitioner affiliated with a subcontractor of the organization must seek approval of services within the subcontractor's own internal review system.

For Medicare purposes, an organization's retrospective review of services is assessed as part of the claims processing function, rather than under these standards. For Medicaid, states may wish to use some parts of the following guidelines in assessing an organization's retrospective, as well as prospective or concurrent, reviews.

3.3.1. The organization follows written policies and procedures, reflecting current standards of medical practice, for processing requests for initial authorization of services or requests for continuation of services.

3.3.1.1. The policies specify time frames for responding to requests for initial and continued determinations, specify information required for authorization decisions, provide for consultation with the requesting provider when appropriate, and provide for expedited response to requests for authorization of urgently needed services.

Time frames and expedited responseMedicare rules establish maximum time frames for an organization to notify an enrollee of an initial determination in response to a request for a service; states may establish their own time limits for Medicaid enrollees, or these may be established in state insurance law. This standard does not set a different maximum time frame for determinations, but requires the organization to establish its own time frames for responding to authorization requests and monitor its own compliance with those time frames. The time frames may vary according to the urgency of the need for the requested service and the complexity of evaluating the request (so long as they do not exceed the applicable legal limits); the organization should be able to demonstrate that its time frames for different types of requests are reasonable in light of these factors.

Note that, under Medicare rules, an enrollee may request an expedited review when the enrollee believes that standard review time frames could jeopardize life, health, or ability to regain maximum functioning. These rules do not apply to Medicaid enrollees, and these guidelines do not specify expedited response requirements for Medicaid contractors. States should develop their own requirements in this area.

Information

The organization must notify affiliated practitioners and providers of the information ordinarily required to process an authorization request, and of the circumstances under which additional information may be required. The organization's information standards must assure that the authorization process is not unduly burdensome for practitioner or provider staff or for enrollees. No information should be required that is not in fact used in the evaluation or recording of the request; in particular, submission of medical records may not be routinely required.

3.3.1.2. Criteria for decisions on coverage and medical necessity are clearly documented, are based on reasonable medical evidence or a consensus of relevant practitioners, and are regularly updated.

An organization may develop its own clinical criteria for review of authorization requests or adopt criteria developed by outside resources. In either case, the organization's procedures must provide that criteria are reviewed before their adoption by affiliated practitioners, and must have mechanisms for periodic re-evaluation of the criteria in the light of scientific advances or changes in customary practice. If the organization has developed standard criteria for approval of a specific procedure or service, these criteria must be made available on request to any enrollee or affiliated provider.

3.3.1.3. Mechanisms are in place to ensure consistent application of review criteria and compatible decisions.

The organization must assure that all employed or contracted reviewers understand coverage policies and review criteria, through manuals, training programs, or other means. In addition, it must periodically assess the consistency of authorization decisions. Possible approaches include review of test cases by different utilization management staff or audits of samples of recent decisions.

3.3.1.4. A clinical peer reviews all decisions to deny authorization on grounds of medical appropriateness.

A clinical peer is, in the case of medical services, a licensed physician. (Some state laws may require that the physician be licensed in the state served by the organization.) For mental health and substance abuse services, a clinical peer is: (a) in the case of requests for inpatient hospitalization, a psychiatrist, a doctoral level clinical psychologist, or, in the case of substance abuse servies, a certified addiction medicine specialist; (b) in the case of requests for other services, a licensed mental health or substance abuse professional. For other services, a clinical peer is an appropriate licensed practitioner (e.g., a dentist for dental services).

No denial of authorization on grounds of medical appropriateness may be issued before the request has been reviewed by the appropriate clinical peer. Other personnel (whether non-clinical, or clinical personnel not meeting the definition of a clinical peer) may approve requests, and may collect information for use by the clinical peer in evaluating a request. However they may issue a denial only on grounds clearly unrelated to medical considerations—for example, because the patient is no longer enrolled, or because the requested service is explicitly excluded from the enrollee's covered benefits. (Benefit determinations involving professional judgment, such as a

determination that a given procedure was experimental, would require review by the clinical peer.)

This standard does not require (although some state laws may) that any authorization request submitted by a specialist be considered by a practitioner in the same specialty. However, the organization must have procedures under which the reviewing clinician may obtain specialty consultations; for example, in considering requests for complex, unusual, or highly specialized services.

3.3.1.5. The requesting provider and the enrollee are promptly notified of any decision to deny, limit, or discontinue authorization of services. The notice specifies the criteria used in denying or limiting authorization and includes information on how to request reconsideration of the decision pursuant to the procedures established under standard 2.4.3. The notice to the enrollee must be in writing.

Again, Medicare has maximum time frames for notice to enrollees, and States may establish their own for Medicaid enrollees. Subject to these maximums, time frames for response are to be specified by the organization in its own procedures.

3.3.1.6. Compensation to persons or organizations conducting utilization management activities is not based, directly or indirectly, on the quantity or type of adverse determinations rendered.

Contracts with individual reviewers or with utilization review organizations may provide for compensation on the basis of time and/or of total numbers of authorization requests processed, but may not include any bonus or other incentive for denial of authorization.

This standard is not meant to meant to apply to physician incentive plans, even though these may sometimes create indirect incentives to deny authorization of some services. For example, if an organization capitates a physician group to provide all ambulatory services for specified enrollees, the physician group may have an internal authorization system for specialty referrals. This is permissible, so long as the payment arrangement for the physician group meets Medicare and Medicaid standards for such arrangements (including standards prohibiting payment for denial of specific services to specific patients). It would not be permissible, however, for the physician group in turn to contract with an outside utilization review entity and then compensate the entity on the basis of service denials.

3.3.1.7. The organization does not prohibit providers from advocating on behalf of enrollees within the utilization management process.

No contract may implicitly or explicitly prohibit a provider from assisting enrollees in obtaining authorization for a service or pursuing reconsideration requests, for example by helping to document medical necessity or supplying scientific evidence of the appropriateness on the requested service. (Note that requesting practitioners are not necessarily parties in reconsiderations under the Medicare process; however, this does not prevent them from assisting the beneficiary in the process.)

3.3.2. All requests for authorization are recorded, along with their disposition, and aggregate data is compiled for use in QAPI.

The organization must collect at least the following information on all requests: requesting practitioner, enrollee, date of the request, service(s) requested, initial response (authorization, including quantity or duration of services authorized, or denial), and date of initial response. In the case of denials which result in a request for reconsideration, the organization must also record the reason for the denial, information used in reconsidering the request, and the ultimate resolution of the request. See standard 1.2.5.2, relating to assessment of authorization activities as part of QAPI.

3.3.3. The organization furnishes information to all affiliated providers about enrollee benefits and utilization management policies.

Provider manuals, supplemented as necessary by bulletins or other updates, must include clear explanations of covered services, including drug formularies and any general coverage decisions with respect to specific procedures or services.**3.4. Practice Guidelines and New Technology**

3.4.1. The organization adopts and disseminates practice guidelines or criteria for the provision of specific services.

The aim of practice guidelines is to assist practitioners and providers in clinical decision making, support consistency in treatment by an organization's affiliated practitioners, and promote improved health care. The organization should have an established mechanism for the adoption of guidelines. If administrative responsibility for development of guidelines is separate from administration of the QAPI program, there should be a system for interface between the two functions. For example, data on compliance with guidelines might be considered in the course of selecting topics for QAPI projects. (Note, however, that an improvement in compliance with guidelines, in the absence of evidence that improved health outcomes resulted, might not meet the requirements for successful QAPI projects as defined under standard 1.4.)

This standard does not impose specific requirements for the number of different guidelines to be adopted or the range of conditions or services to be covered, although at least some guidelines should address areas other than preventive services. Each organization must develop its own priorities for development of new guidelines on the basis of population needs or identified variations in practice patterns within the organization.

3.4.1.1. Guidelines are based on reasonable medical evidence or a consensus of relevant practitioners, are developed in consultation with affiliated providers, and are reviewed and updated periodically.

An organization may adopt established national guidelines, such as those promulgated by the Agency for Health Care Policy and Research, but should also have a process for developing new guidelines targeted to its own needs. (In regional or national organizations, this process may be centralized.) There should be a formal mechanism for consulting affiliated practitioners as guidelines are developed and for reevaluating guidelines on a periodic basis.

3.4.1.2. Guidelines are communicated to providers and, as appropriate, to enrollees.

Guidelines must be disseminated through provider manuals, newsletters, or other communications. In addition, guidelines likely to be of interest to enrollees should be disseminated through enrollee newsletters and other educational materials. Possible examples might be guidelines that include recommendations relating to self-care or that relate to services the enrollee can initiate, such as immunizations or periodic screenings.

3.4.1.3. Decision making in utilization management, enrollee education, interpretation of covered benefits, and other areas to which the guidelines are applicable is consistent with the guidelines.

Practice guidelines are advisory documents, intended to assist practitioners without superseding independent clinical judgment, and are not identical to review criteria or coverage determinations. However, decision making in these and other functional areas should not be inconsistent with the practitioner consensus on the basis of which guidelines are developed. Enrollee education efforts should include information on guidelines for preventive care.

Performance indicators selected for a QAPI project should, to the extent feasible, include measures of providers' compliance with guidelines that are relevant to the topic.

3.4.2. The organization implements written policies and procedures for evaluating new medical technologies and new uses of existing technologies.

For the purpose of this standard, new technologies include clinical interventions, procedures, pharmacological treatments, and devices. There must be an identifiable official or unit within the organization responsible for evaluation of technologies. The organization's policies must specify criteria to be used in this evaluation and must establish procedures for: collection of scientific evidence; review of findings by the Food and Drug Administration and other regulatory bodies; consultation with affiliated practitioners and outside experts; and communication of coverage decisions to providers.

3.4.2.1. The evaluations take into account coverage decisions by Medicare intermediaries and carriers, national Medicare coverage decisions, and federal and state Medicaid coverage decisions, as appropriate.

Organizations with Medicare and Medicaid enrollees may not adopt policies that uniformly exclude from coverage services or items approved under national Medicare coverage determinations (although financial responsibility for newly approved services may be delayed under section 1876(d)(2)(B) of the Social Security Act), coverage policies of local Medicare intermediaries or carriers, or coverage decisions by the Medicaid agency. When more than one Medicare intermediary or carrier serves an organization's service area, the applicable coverage policy for any given enrollee is that of the intermediary or carrier serving the area in which that enrollee resides.**3.5. Provider**

Qualification and Selection. The organization implements a documented process for selection and retention of affiliated providers.
The organization must have written policies and procedures, approved by the policymaking body, for the selection of practitioners and providers. The policies should include criteria for credentialing of practitioners that are appropriate to the nature of the services they will be furnishing to enrollees. The process of provider selection should be integrated with the process, specified under standard 3.1, of establishing and maintaining an adequate network.

3.5.1. For each physician or other individual practitioner, including each practitioner within a contracting group who provides services to the organization's enrollees, the process includes:

3.5.1.1. Procedures for initial credentialing, including a written application, verification of licensure and other information from primary sources, and site visits as appropriate.

Credentialing is the review of qualifications and other relevant information pertaining to a practitioner who seeks appointment (in the case of an organization directly employing practitioners) or who seeks a contract with the organization. Credentialing is required for all physicians and all other types of practitioners who provide services to the organization's enrollees and who are permitted to practice independently under state law. Credentialing is *not* required for: practitioners who are permitted to furnish services only under the direct supervision of another practitioner; hospital-based practitioners who provide services to enrollees incident to hospital services, unless those practitioners are separately identified in enrollee literature as available to enrollees; or students, residents, or fellows.

The credentialing process, including application, verification of information, and a site visit (if applicable) must be completed before the initial appointment of or contract with the practitioner. The information collected must be no more than 6 months old on the date on which the practitioner is determined (for example, by a credentialing committee) to be eligible for the appointment or contract.

Application
The applicant completes an application for appointment or affiliation. The application includes a work history covering at least five years and a statement by the applicant regarding: any limitations in ability to perform the functions of the position, with or without accommodation; history of loss of license and/or felony convictions; and history of loss or limitation of privileges or disciplinary activity.

Verification of information
The following must be verified from primary sources and included in credentialing records:

1. a current valid license to practice;
2. if applicable, clinical privileges in good standing at the hospital designated by the practitioner as the primary admitting facility;
3. if applicable, a valid Drug Enforcement Agency (DEA) or Controlled Dangerous Substances certificate (CDS);

4. education and training, including evidence of graduation from the appropriate professional school and completion of a residency or specialty training, if applicable;
5. board certification if the practitioner states that he/she or is board certified on the application;[1]
6. current, adequate malpractice insurance meeting the organization's requirements; and
7. a history of professional liability claims that resulted in settlements or judgments paid by or on behalf of the practitioner. (This information can be obtained from the malpractice carrier or from the National Practitioner Data Bank.)

In addition, the organization must obtain and include in its credentialing records:

8. for physicians, information from the National Practitioner Data Bank;
9. information about sanctions or limitations on licensure from the applicable state licensing agency or board, or from a group such as the Federation of State Medical Boards;
10. information on previous sanction activity by Medicare and Medicaid. (This may be obtained through the HHS Medicare and Medicaid Sanctions and Reinstatement Report or through direct contact with the Medicaid agency or the Medicare intermediary.)

Site visit

The organization's procedures must provide for a site visit to the office of each primary care practitioner (as defined by the organization under standard 3.2.1.2) and to high-volume specialists or other high-volume licensed practitioners, including high-volume non-physician practitioners. The procedures must specify the criteria for determining that a practitioner is "high-volume." A repeat site visit is not required for a new practitioner in a setting already visited.

Site visits must be conducted by clinical personnel (or teams including clinical personnel). They should include an evaluation of the site's accessibility, appearance, and space, and of the adequacy of equipment, using standards developed by the organization. In addition the visits should determine whether the site conforms to the organization's standards for medical record keeping practices (as required under standard 3.6.1) and confidentiality requirements (established pursuant to standard 2.2.1).

3.5.1.2. Procedures for recredentialing, at least every two years, through a process that updates information obtained in initial credentialing and considers performance indicators collected through the QAPI program, the utilization management system, the grievance system, enrollee satisfaction surveys, and other activities of the organization.

[1] As is noted under standard 3.1.1.1, there is no requirement that practitioners be board certified. However, certification must be verified if the organization intends to represent, in its enrollee literature or otherwise, that its practitioners are certified.

The following must be re-verified from primary sources: licensure; clinical privileges, malpractice coverage, and history of professional liability claims. Board certification must be verified only if the practitioner was due to be recertified or states that he or she has become board certified since the last time he or she was credentialed or recredentialed. In addition, the organization must re-query the National Practitioner Data Bank and obtain updated sanction or restriction information from licensing agencies, Medicare, and Medicaid. Site visits should be repeated for the practitioners specified as requiring site visits under standard 3.5.1.1; multi-practitioner sites should be visited every two years.

3.5.1.3. A process for receiving advice from affiliated practitioners with respect to criteria for credentialing and recredentialing of individual practitioners.

Credentialing standards for types of practitioners and for specialists should be reviewed by clinical peers, through establishment of a credentialing committee or other mechanism. In addition, there should be a process for peer review when the organization is considering employing or contracting with a practitioner who does not meet its established credentialing standards.

3.5.1.4. Written policies and procedures for suspending or terminating affiliation with a contracting physician, including an appeals process.

A formal process, including an opportunity for appeal, must be followed when an organization is suspending or terminating a physician's contract. The organization must notify all physicians of its rules regarding affiliation with the organization, provide advance notice of adverse decisions, and provide for appeal including an opportunity for presentation of information and views of the physician.

3.5.2. For each institutional provider or supplier, the organization determines, and redetermines at specified intervals, that the provider or supplier:

3.5.2.1. Is licensed to operate in the state, and in compliance with any other applicable state or federal requirements;
3.5.2.2. Is certified as meeting the requirements of Medicare or Medicaid (as applicable); is reviewed and approved by an approved accrediting body; or is determined by the organization to meet standards established by the organization itself; and

Accrediting bodies include the Joint Commission on Accreditation of Healthcare Organizations (JCAHO), the Accreditation Association for Ambulatory Health Care, the Commission on Accreditation of Rehabilitation Facilities, the Council on Accreditation, the Community Health Accreditation Program (CHAP), and the Continuing Care Accreditation Commission. This standard does not require that an organization accept the findings of an accrediting body in determining whether to contract with a provider, or that it reject providers that are not accredited. However, an organization that does not rely on independent accreditation must either (a) rely on determinations by Medicare or Medicaid or (b) develop its own standards for approval of providers and

determine that the providers meet those standards before including them in its network.

Primary source verification of accreditation and licensure are not required, unless otherwise provided in the organization's Medicare or Medicaid contract; that is, the organization may rely on documentation supplied by the provider. Current documentation should be obtained at least every three years, and contracts should provide for notice from the provider of any change in its licensure or accreditation status.

3.5.2.3. In the case of a provider or supplier providing services to Medicare enrollees, is approved for participation in Medicare. (Note: This requirement does not apply to providers of additional or supplemental services for which Medicare has no approval standards.)

Regardless of the organization's usual policies for determining that an institutional provider or supplier is qualified to serve its enrollees, an organization with a Medicare contract must assure that its Medicare enrollees are served only by Medicare-approved providers/suppliers. Specific types of providers/suppliers for whom evidence of Medicare approval is required include:

1. Hospitals (JCAHO accreditation or Medicare certification)
2. Laboratories (Exemption from CLIA or a HCFA-issued registration certificate, certificate, or certificate of waiver or accreditation)
3. Skilled nursing facilities
4. Comprehensive outpatient rehabilitation facilities
5. Outpatient physical therapy and speech pathology providers
6. Rural primary care hospitals
7. Home health agencies
8. Ambulatory surgery centers
9. Providers of end-stage renal disease services

For organizations with Medicaid enrollees, states may establish their own standards with respect to whether providers affiliated with the organization must meet standards for Medicaid fee-for-service participation.

3.5.3. The organization notifies licensing or disciplinary bodies or other appropriate authorities when a practitioner's or provider's affiliation is suspended or terminated because of quality deficiencies.

3.6. Enrollee Health Records and Communication of Clinical Information. The organization implements appropriate standards to assure that the organization and its providers have the information required for effective and continuous patient care and for quality review, and conducts an ongoing program to monitor compliance with those standards.

3.6.1. The organization assures that each provider furnishing services to enrollees maintains an enrollee health record in accordance with standards established by the organization, taking into account professional standards.

3.6.1.1. The organization enforces standards for health record content and organization, including specifications of basic information to be included in each health record.

At a minimum, each record should include:

1. Identifying information on the enrollee;
2. Identification of all providers participating in the enrollee's care and information on services furnished by these providers obtained pursuant to standard 3.6.2;
3. A problem list, including significant illnesses and medical and psychological conditions;
4. Presenting complaints, diagnoses, and treatment plans;
5. Prescribed medications, including dosages and dates of initial or refill prescriptions;
6. Information on allergies and adverse reactions (or a notation that the patient has no known allergies or history of adverse reactions);
7. Information on advance directives;
8. Past medical history, physical examinations, treatment necessary, and possible risk factors for the enrollee relevant to the particular provider.

3.6.1.2. The organization implements a process to assess and improve the content, legibility, organization, and completeness of enrollee health records.

The organization must include a review of practitioners' record-keeping practices as part of site visits required under standard 3.5. This review should also assess each practitioner's or provider's procedures for assuring confidentiality of medical and health information, as required under standard 2.2.1.1. The organization must have procedures for following up on deficiencies identified during site visits to practitioners and providers, as well as deficiencies identified in records obtained from any affiliated provider in the course of QAPI or other record reviews.

3.6.1.3. Enrollee health records are available and accessible to the organization and to appropriate state and federal authorities, or their delegates, involved in assessing the quality of care or investigating enrollee grievances or complaints.

Contracts with providers must specify that records will be made available to government reviewers, peer review organizations, external quality review organizations, or other authorized entities.

3.6.2. The organization assures appropriate exchange of information among providers, such that:

The requirements in this standard must be included in all provider agreements. Review of compliance should occur as part of reviews of recordkeeping practices under standard 3.6.1.2.

3.6.2.1. A provider making a referral transmits necessary information to the provider receiving the referral;

3.6.2.2. A provider furnishing a referral service reports appropriate information to the referring provider;

3.6.2.3. Providers request information from other treating providers as necessary to provide care; and

Organizations that offer a point-of-service benefit, that allow enrollees to access in-network non-primary care services without authorization, or that serve dually eligible Medicare/Medicaid beneficiaries should emphasize in their educational materials the need for enrollees to inform their primary care providers about the services they obtain.

3.6.2.4. If the organization offers a point-of-service benefit or other benefit providing coverage of services of non-network providers, the organization transmits information about services used by an enrollee under the benefit to the enrollee's primary care provider.

Information transmitted to the primary care provider must be sufficient to allow that provider to request additional information on the services in compliance with standard 3.6.2.3.

4. Delegation. The organization oversees and is accountable to HCFA or the State for any functions or responsibilities that are described in these standards and that are delegated to any contractor.

With certain restrictions indicated below, an organization may, by written contract, delegate any activity required under or governed by these standards to another entity. An organization entering into a Medicare or Medicaid contract remains entirely accountable to HCFA or the State for performance of any delegated function. It is the sole responsibility of the organization to assure that the function is performed in accordance with applicable standards. (Note that this standard is not meant to imply that the organization is legally liable for the actions of its subcontractors, for example in cases of malpractice; any such liability is established by State or local law.)

Special note must be made of "carve-out" arrangements, under which an organization contracts with an entity to assume entire responsibility for a given type or category of service and delegates to that entity a broad range of basic management functions.[1] Such contracts are, perhaps, most common for mental health and substance abuse services, although some organizations use similar arrangements for prescription drugs, home health care, or other types of services. These arrangements are conceptually no different from those under which an organization capitates a single medical group to provide all physician and related ambulatory services and delegates management of those services to the group. Although the latter arrangements are never spoken of as "medical carve-outs," they are functionally comparable to "mental health/substance abuse carve-outs": the contractor assumes entire responsibility for management of a defined portion of the overall benefit package. Just as medical group contracts have never diminished the basic accountability of the organization directly contracting with Medicare or Medicaid, so with mental health or other carve-outs. The prime contractor remains wholly accountable for the activities of its subcontractors.

Because of the wide variety of organizational structures and contractual arrangements, it is difficult to develop simple guidelines for the review of delegated activities. In any given situation, the review methodology to be adopted should be that which is least burdensome for reviewers and for the organization, yet which provides positive assurance that the activity in question is being performed in compliance with these standards. For example, credentialing of practitioners might occur in several different ways:

- The organization itself verifies the credentials of individual practitioners affiliated with its subcontractors. Review would focus directly on the organization's performance of this function.
- An organization contracts with one or more independent physician groups, each of which is expected to verify the credentials of each affiliated practitioner. It would be impractical for a HCFA or State reviewer to review compliance by the independent contractor(s). Instead, the organization itself must document that it has periodically reviewed the performance of each contractor, for example by verifying that all

[1] This is to be distinguished from situations in which a state "carves out" specific services—that is, excludes them from its Medicaid contract with an organization. See the introduction for a discussion of the applicability of these guidelines to contracts that are less than comprehensive.

required credentialing information is present in a sample of each contractor's practitioner records.

- An organization contracts with a single independent credentialing verification organization (CVO) to collect information about practitioners. The CVO, and not the organization, maintains documentation of verification of credentials from primary sources. If a single CVO provided services to multiple organizations in a state, a state Medicaid agency might review the CVO itself and deem in compliance all organizations that contracted with the CVO. Alternatively, the state might accept the findings of an independent body that accredits CVOs. For the purposes of Medicare, however, HCFA does not at this time review CVOs or accept external accreditation of CVOs. It would therefore expect the organization to document that it has monitored the CVO's performance, again through a review of a sample of practitioner records. (Similarly, the organization would be required to review the credentialing performance of any "carve-out" contractor, such as a national managed behavioral health care organization.)

Again, as this single example illustrates, the variety and complexity of contracting arrangements makes it impractical to suggest a uniform method for review of delegated functions. As part of the advance preparation for on-site reviews, the reviewer and the organization should negotiate the most expeditious procedure. However, the burden of documenting a delegate's compliance with applicable standards ultimately rests with the organization.

4.1. The following basic requirements apply to all delegated functions:

4.1.1. A written agreement specifies the delegated activities and reporting responsibilities of the contractor and provides for revocation of the delegation or other remedies for inadequate performance.

Contracts must indicate what functions have been delegated and must require the contractor to comply with the requirements of these standards and of applicable law and regulations. When a function is only partially delegated, contract provisions must clearly delineate which responsibilities have been delegated and which remain with the organization. In the QAPI area, for example, the organization might develop topics for projects in consultation with an affiliated medical group but delegate the actual conduct of a specific project to the group. The agreement must specify how the delegate is to conduct QAPI activities, at what points in the process decisions by the delegate (for example, on data collection methodologies) are subject to the organization's review, and how the delegate's activities will be integrated into the organization's overall QAPI program (for example, through participation in an organization-wide committee).

It is especially important to identify instances in which a delegation has been made implicitly. For example, a contract with a medical group may hold the group responsible for providing or arranging for a wide range of ambulatory services in return for a fixed monthly capitation payment. The group is left to develop its own procedures for approving requests for referral services by its own primary care practitioners. If so, the utilization management function has been delegated, and the organization must assure that the group complies with the standards for that function, including standards related to requests for expedited review.

4.1.2. The organization evaluates the contractor's ability to perform the delegated activities prior to delegation.

The organization must document that it has approved the contractor's policies and procedures with respect to the delegated function, and must verify that the contractor has devoted sufficient resources and appropriately qualified staff to performing the function.

4.1.3. The performance of the contractor is monitored on an ongoing basis and formally reviewed by the organization at least annually.

The organization must have written procedures for monitoring and review of delegated activities. The nature of ongoing monitoring may vary according to the organization's past experience with the delegate and with the nature of the delegated activity. In the areas of grievance processing or utilization management, for example, monitoring may be more or less continuous, in as much as decisions by the delegate may be appealed to the organization. However, the organization must periodically verify that the delegate is in fact forwarding requests for reconsideration, and that its statistical or other reporting on these processes is accurate. In other areas, such as credentialing, annual review of the delegate's activities may be sufficient, particularly if the organization has ascertained in the past that the delegate is performing the activity properly.

The annual evaluation should be a comprehensive assessment of the delegate's performance, including both compliance with applicable standards and the extent to which the delegate's activities promote the organization's overall goals and objectives for the delegated function. If any problems or deficiencies are identified, the evaluation must specify any necessary corrective action and include procedures for assuring that the corrective action is implemented.

The organization must assure that monitoring of delegates is carried out by staff of the organization who are qualified to assess the delegates' activities. For example, an organization that has delegated authorization of mental health and substance abuse services to a contractor must use appropriately credentialed professionals to review the contractor's authorization decisions.

4.2. The following restrictions apply to delegation of certain functions:

4.2.1. An organization with Medicare enrollees may fully delegate the authorization functions described in standard 3.3 to a contractor, but may not fully delegate the reconsideration process described in standard 2.4.3, and may not delegate any part of this process to a contractor that is unable to comply with standard 2.4.3.3.

The reconsideration process may not be fully delegated because the organization, and not a subcontractor, is responsible for forwarding to HCFA's reconsideration contractor all cases in which the reconsideration does not result in a decision fully favorable to the enrollee. Most organizations will presumably wish to conduct their own review of such cases; they must in any event receive them from the subcontractor and transmit them to the reconsideration contractor as decisions of the organization. As was noted earlier, no part of the reconsideration process may be delegated to a solo practitioner, as the practitioner would be in the position of reviewing his or her own initial determination.

As in the case of any other delegated function, the organization is responsible for overseeing the contractor's performance and assuring its compliance with these standards and other Federal and state requirements. In particular, it is critical that the organization has procedures to assure that steps in the authorization, reconsideration, and grievance processes are completed within the time limits established for those processes.

4.2.2. If the organization delegates selection of practitioners or providers to another entity, the organization retains the right to approve, suspend, or terminate any individual practitioner, site, or provider selected by that entity.

All contracts with medical groups or other entities serving Medicare or Medicaid enrollees must include this provision, so that the organization can assure that enrollees are not served by any practitioner or provider excluded from program participation.

CHAPTER 4: IMPLEMENTATION WORKPLAN

QISMC departs from traditional federal and state oversight activities in several important ways:

- It is no longer sufficient for a plan to comply with structure and process standards; there must be demonstrated improvement in quality;
- More rigorous and consistent methods will be employed when assessing whether a plan's quality management program satisfies standards;
- There are enhanced opportunities for sharing review activities and using findings of other oversight entities and private accrediting bodies; and
- Greater reliance is placed on the collection and use of credible data.

The following section examines the technical and support resources HCFA, states, their delegates and managed care plans require to implement QISMC. The proposed work plan will guide decisions with respect to initial training as well as ongoing technical assistance needs. Comments solicited during the public review period will be used to further refine and develop this work plan. Finally, for it to work, QISMC requires a HCFA/State partnership. Reviewers are encouraged to consider ways in which the intent and scope of QISMC can be met through these and other collaborative activities.

1. **Develop and test reviewers' monitoring guide for assessing plan's compliance to QISMC standards.**

QISMC contains standards and guidelines for use by reviewers in assessing compliance. Reviewers will require further guidance, however, to determine the appropriate methods for both data collection (e.g., personal interviews, medical record reviews, onsite documentation, desk reviews) and scoring. Protocols must be developed and tested for gathering and assessing data under each QISMC standard and scoring a plan's level of compliance. In addition, protocols must be developed for working with plans in developing improvement strategies or defining appropriate actions when problems are identified. Finally, testing must be conducted to enhance inter-rate reliability in applying the protocols among reviewers and across plans.

2. **Conduct workshops to promote shared learning about QISMC among federal and state policy makers, consumers, Peer Review Organizations (PROs), accrediting bodies, and managed care plans.**

QISMC lays out the standards and reviewer guidelines for assessing a plan's internal quality improvement program. The purpose of workshops will be to:

- Assure a common interpretation of standards and reviewer guidelines;

- Clarify where separate standards apply for Medicare and Medicaid;
- Train in the use of reviewers' protocol;
- Examine options for coordinating reviews between Medicare and Medicaid;
- Assess opportunities for sharing reviews and/or findings among public and private review entities;
- Consider implications of QISMC for the federally mandated external quality reviews;
- Review QISMC within the context of other quality improvement tools and practices (e.g., performance measurement)

Regional workshops will be designed to bring key stakeholders together to consider new approaches for working collaboratively in their oversight activities.

3. **Prepare collaborative strategies for conducting reviews under QISMC.**

QISMC provides the standards and tools for reviewing the performance of managed care plans but does not define the role to be played by public and private review organizations in fulfilling its provisions. For example, QISMC defines a set of common review standards for use by Medicare and Medicaid but does not specify whether HCFA and states should conduct separate or joint compliance reviews, or if findings from one entity's review should satisfy the requirements of the other. Similarly, to the extent that QISMC standards are equivalent to those of other public and private review organizations, QISMC does not direct HCFA and states on how best to coordinate review activities with these other entities.

The workshops will solicit feedback on how federal and state purchasers can work collaboratively together and with other state agencies and private review organizations to promote quality. Many approaches are likely to surface with no single method seen as the only solution. Following the workshops, case scenarios will be developed which define and document models for conducing reviews. These will serve as guidance to purchasers as they construct their

4. **Develop a mechanism for the periodic review, evaluation and revision of QISMC standards and reviewer guidelines.**

At the time of its publication, QISMC will represent state-of-the-art standards for evaluating care quality. Once promulgated and used, new issues are likely to emerge which will suggest the need for different or revised standards and review approaches. In its role as a standard-setting agency, HCFA must develop a standing committee or other mechanism to assure that standards: (1) keep current with developments in health care delivery, managed care, and quality measurement; and (2) are valid and reliable. In addition, reviewer guidelines must be revised as issues surface in their application over time.

5. **Establish mechanisms for ongoing assistance to federal and state reviewers as they apply the QISMC standards and reviewer guidelines to their managed care programs.**

Initial workshops will provide opportunities to learn about QISMC and assess its implications for federal and state purchasers. While these workshops will be important to bring everyone up to a common understanding, they must be supplemented with ongoing technical assistance as reviewers gain experience in their application. Technical assistance may be in the form of "help" lines, bulletins, or training seminars.

APPENDIX A

Membership List
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January 6, 1998

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DRAFT

A Report to the Florida Legislature

The Feasibility of Medicaid Expansion for Persons with HIV

The Agency for Health Care Administration

March 1998

DRAFT

The Feasibility of Medicaid Expansion for Persons with HIV

EXECUTIVE SUMMARY

The advent of effective drug therapies is significantly changing how health care is delivered to persons with HIV/AIDS. The current standard of care for persons with HIV calls for clinical intervention, including the use of expensive combination drug therapies, at the earliest stage of HIV infection. The emergence of new treatment protocols is increasing the demand for drug therapy for many persons living with HIV. While advances in treatment have prompted unprecedented hope in the fight against AIDS, serious gaps in access to care and treatment for persons with HIV remain.

Medicaid is the largest single payor of direct medical care for persons with AIDS. Currently, it is estimated that Florida Medicaid spends over $340 million on AIDS-related services for over 26,000 individuals with AIDS/HIV. Cost projections indicate Medicaid expenditures will reach $600 million within the next five years. However, Medicaid does not cover all low-income individuals. Disability requirements related to Supplemental Security Income (SSI) eligibility dictate that many low-income persons with HIV develop AIDS before accessing health services.

In 1997, the Florida Legislature directed the Agency for Health Care Administration to:

> **"pursue with the federal Health Care Financing Administration (HCFA) the feasibility and potential for a Medicaid waiver for services to persons with AIDS. Included in the options shall be the issues of waiving the requirement of prior SSI eligibility, of limiting Medicaid coverage to selected services (i.e. prescribed medications), and permitting a Medicaid 'Buy-In' for services."**

Federal law allows states some flexibility to expand access, improve quality of care, or contain costs within the Medicaid program under waivers approved by HCFA. Research and demonstration projects (1115 waivers) enable Medicaid to expand eligibility to targeted populations not currently covered, and limit the availability of some services to such populations. Medicaid research and demonstration projects must be budget neutral for the approved five-year period.

Considerable discussion of a Medicaid research and demonstration waiver for persons with HIV was generated when the Clinton Administration announced plans to explore expanding Medicaid to ensure that low-income individuals who are HIV positive (HIV+) could access new combination drug therapies. HCFA has examined the nationwide costs of providing Medicaid coverage to low-income persons with HIV not currently covered under Medicaid. To date, HCFA has not determined that increased access to combination drug therapies could be accomplished in a budget neutral environment.

The Florida Department of Health estimates that there are between 65,000 and 100,000 persons infected with HIV in Florida, and the fiscal implications of a broad based Medicaid expansion are significant. The cost analysis presented in this report also fails to yield a clear demonstration of the five year cost effectiveness of expanding limited Medicaid benefits to certain low-income persons with HIV/AIDS (at or below 100 percent of the Federal Poverty Level). Costs for expanding Medicaid coverage to all persons who are HIV+ for prescription medication, physician services, lab/x-rays, and case management may exceed an additional $1.7 billion over the next five years. Focusing Medicaid expansion on low-income individuals who have been diagnosed with AIDS, but do not meet SSI disability criteria would be less costly; approximately $7.7 million over five years. Even this more limited expansion would require significant savings in Medicaid AIDS-related expenditures (29 percent) to be budget neutral over the proposed demonstration period.

Florida Medicaid has met with HCFA to discuss strategies for expanding access to Medicaid for persons with HIV. State and federal agencies, as well as researchers and private foundations, are continuing to examine the cost implications of expanding Medicaid coverage to individuals with HIV prior to their eligibility through disability determination. Due to the rapidly changing nature of HIV/AIDS treatment, the full implications of the potential expansion of Medicaid remain unclear.

In light of these issues, it is recommended to the Florida Legislature that:

- **The Agency for Health Care Administration should continue to implement and expand disease management for persons with HIV/AIDS; promote the use of home and community-based services over more costly institutional care; and develop a more in-depth analysis of projected cost savings from such disease management initiatives that might be available to finance expanded Medicaid coverage to persons with HIV/AIDS.**

- **The Agency for Health Care Administration, in conjunction with the Department of Health, should continue to work with officials in the Health Care Financing Administration, and researchers in the academic community to refine cost models, clarify common assumptions, and develop more detailed projections necessary to demonstrate the potential for expanded Medicaid coverage for persons with HIV/AIDS under the condition of Medicaid budget neutrality.**

As the Agency for Health Care Administration continues to research the feasibility of a Medicaid waiver to expand eligibility beyond SSI disability requirements, many persons infected with HIV will continue to have limited access to effective treatment that could help to slow the progression of their disease. Approval of a Medicaid research and demonstration process by the Health Care Financing Administration would likely be an involved, and lengthy, process; further delaying greater access to combination drug therapy for persons with HIV. Therefore, it is recommended that the Florida Legislature authorize the Agency for Health Care Administration to move forward in expanding Medicaid coverage and to seek a Medicaid waiver if cost neutrality can be demonstrated.

DRAFT

The Feasibility of Medicaid Expansion for Persons with HIV

BACKGROUND

HIV stands for Human Immunodeficiency Virus, a retrovirus that infects cells of the immune system. HIV can cause Acquired Immunodeficiency Syndrome (AIDS), a condition that gradually destroys the bodies immune system and makes the body vulnerable to opportunistic diseases. Many people refer to HIV as the "AIDS virus".

When HIV enters the body, it infects white blood cells (called CD4+ lymphocytes). These cells are key elements in the body's immune system. The genetic material of HIV causes these CD4+ cells to produce multiple copies of the virus, which emerge to infect additional cells. This process also results in the destruction of these cells and the lymphatic glands that produce them. The process weakens the body's ability to fight infection. As HIV destroys the immune system, the individual becomes susceptible to increasingly severe and frequent episodes of opportunistic infections.

Even in the early course of HIV infection when the infected person may feel and look fine, i.e. is "asymptomatic", he or she can give the virus to someone else through the various modes of transmission. HIV can be transmitted through unprotected sexual intercourse with an HIV infected person, sharing drug injection equipment, or being accidentally pierced by needles or sharp objects contaminated with infected blood. The virus can be transferred from mother to child during pregnancy, childbirth or breast-feeding. HIV can also be transmitted by infected blood used in transfusions, infected blood products used in the treatment of certain diseases and disorders such as hemophilia, and transplanted organs from infected donors (since 1985, federally mandated screening and treatment of the blood supply has reduced the risk of transmission through this route to 1 in 255,000; routine screening of organ donors also began in 1985).

A person with HIV infection may be asymptomatic and remain healthy for years. However, HIV creates billions of new viral copies in the body each day. The body's natural reaction to the infection is to produce billions of white blood cells to fight HIV. But untreated HIV is able to replicate faster than the body can attack it. The opportunistic illnesses, which result in the diagnosis of AIDS, tend to occur later in the infection, when few CD4+ cells remain. Eventually, in most people, the process leads to death, however, disease progression may be significantly slowed by treatment with anti-retroviral drugs.

New Treatment Protocol - Combination Drug Therapy

The advent of effective drug treatments is significantly changing how health care is delivered to persons with HIV/AIDS. The National Institutes of Health (NIH) now advises comprehensive care and treatment, often with combination drug therapy, from the earliest stages of HIV disease. The new standard of care for people with HIV emphasizes early clinical intervention, calling for both primary care and combination drug therapy, including protease inhibitors, at earlier stages of infection. The emergence of clinical treatment guidelines is increasing the demand for drug therapy for many persons living with HIV.

Since HIV is classified as a retrovirus, the primary pharmaceutical strategy for treatment is the use of anti-retroviral drugs. There are currently two classes of these drugs used in the treatment of HIV/AIDS. The first is known as "reverse transcriptase inhibitors" (RTIs). These drugs work by neutralizing an enzyme called reverse transcriptase, which HIV needs at the beginning of its reproductive life cycle. The other class of drugs more recently developed are called "protease inhibitors" (PIs). These drugs act to neutralize yet another enzyme, protease, that HIV needs near the end of its reproductive life cycle. In many HIV/AIDS patients, doctors have found that treatment with a combination of RTI's and PI's has been successful in reducing the level of virus in the patient's blood to undetectable levels. Many of these patients experience dramatic improvements in their functional health. Many experts now suggest that the best opportunity to slow the progression of HIV infection is provided by the initiation of potent combination anti-retroviral therapy during primary infection. Other researchers have developed mathematical models to suggest that patients caught early enough and treated with combination drug therapy could be free of HIV in two to three years. While complete elimination of the HIV virus from the body has not been demonstrated, combination drug therapies have proven effective for many, driving viral loads (the amount of virus in the blood) below detectable levels, significantly slowing disease progression and maintaining or dramatically improving overall health.

Persons with HIV/AIDS

Nearly 500,000 people in the United States have been diagnosed with AIDS, more than 300,000 have died. In less than 15 years, AIDS has become the principal killer of all Americans between the ages of 25 and 44. As of September 30, 1997, there have been 63,700 total cases of persons with AIDS reported in Florida since 1981. The Florida Department of Health estimates that there are currently 26,800 persons living with AIDS in Florida; 42 percent of the cumulative cases reported since 1981. For the first time since the beginning of the AIDS epidemic, there has been a decrease in the number of

Americans dying from AIDS. The U.S. Centers for Disease Control (CDC) reported a 13 percent decline in the number of AIDS-related deaths for the first six months of 1996, as compared to the same period in 1995. Generally, national trends related to HIV and AIDS tend to be born out in Florida. AIDS deaths in the state declined 29 percent in 1996 as compared to the same period in 1995.

AIDS cases have been reported since 1981. Florida has only recently implemented HIV reporting, effective July 1, 1997. Therefore, at this time, the actual number of individuals who are infected with HIV is unknown. While more accurate information is anticipated in the future, figures available for HIV prevalence are estimates. The Florida Department of Health estimates that between 65,000 and 100,000 persons are infected with HIV/AIDS in Florida.

FIGURE 1: Estimated Prevalence of HIV in Florida, by District

Region	Point	Minimum	Maximum
State	82,500	65,000	100,000
(Department of Health Districts)			
District 1	1,300	650	2,000
District 2	1,200	600	1,800
District 3	900	450	1,400
District 4	4,500	3,000	6,100
District 5	3,600	2,300	4,900
District 6	5,600	3,900	7,300
District 7	7,300	5,100	9,500
District 8	3,200	2,100	4,300
District 9	7,900	5,500	10,300
District 10	12,800	9,200	16,400
District 11	25,600	19,200	32,000
District 12	1,000	500	1,500
District 13	900	450	1,400
District 14	1,400	700	2,100
District 15	1,900	1,200	2,600

MEDICAID FOR PERSONS WITH AIDS/HIV

Medicaid is a program authorized by Title XIX of the Social Security Act that provides medical assistance to certain low-income individuals and families. Established in 1965, the Medicaid program is administered by the states, but jointly financed by the federal and state governments. The Health Care Financing Administration (HCFA) is the federal agency responsible for oversight

of the Medicaid program. While figures vary widely from state to state, HCFA estimates that, nationally, Medicaid serves over 50 percent of all AIDS patients and up to 90 percent of all children with AIDS. Medicaid is the largest single payer of direct medical care services for people with AIDS. Combined federal and state national Medicaid expenditures for AIDS-related care in federal fiscal year (FFY) 1997 are estimated at $3.3 billion; 1.8 percent of the nation's total Medicaid payments in this fiscal year. The outlays are projected to reach $4.1 billion per year by FFY 2000.

Medicaid Services

Federal law requires states to develop a State Medicaid Plan that provides a minimum benefit package of certain mandatory services. States can also elect to cover a wide variety of optional benefits. The federal government pays a portion of the total medical assistance expenditures, for each state's Medicaid program. Federal payments to states for medical assistance under Medicaid has no set limit. The federal government matches state expenditures for covered services to eligible individuals based on an established rate of federal financial participation (FFP). This federal matching ratio, called the Federal Medical Assistance Percentage (FMAP), is determined annually. Florida's FMAP, or federal matching rate is approximately 56 percent; Florida receives about $.56 in federal financial participation for every $1.00 spent on allowable Medicaid services.

Medicaid Eligibility

Within parameters of federal law, states have some discretion in determining who will be covered by Medicaid and the financial criteria for Medicaid eligibility. To receive Medicaid benefits, low-income individuals must meet certain categorical requirements. Some categorically eligible individuals may be receiving a income maintenance payment such as Supplemental Security Income (SSI) or Aid to Families with Dependent Children (AFDC), now referred to as Temporary Assistance for Needy Families-TANF. Categorically needy programs also cover certain mandatory low-income children and pregnant women who do not receive cash assistance.

States may elect to provide Medicaid benefits to other categorically related groups, whose coverage is not mandated by federal law. Florida has elected to provide Medicaid coverage to certain SSI-related eligibility groups. Medicaid for the Aged and Disabled (MEDS-AD) extend the full array of Medicaid services to individuals with incomes up to 90 percent of the Federal Poverty Level (FPL) who do not receive cash assistance under SSI. Florida's Institutional Care

Program (ICP) provides full Medicaid coverage to individuals under a higher monthly income level (300 percent of the SSI federal benefit rate) who are institutionalized or served through home and community-based services as an alternative to placement in a Nursing Facility or Intermediate Care Facility for the Developmentally Disabled (ICF/DD). Florida also provides Medicaid coverage through the Medically Needy program, which covers individuals whose income is too high to qualify for other coverage groups, but who have large monthly medical bills. MEDS-AD, ICP and Medically Needy coverage are said to be SSI-related because these eligibility groups also require an individual to be aged or disabled as well as low-income, to receive Medicaid services. Unlike categorical eligibility under AFDC, SSI-related recipients must be determined to have a physical or mental disability, or be age 65 or older.

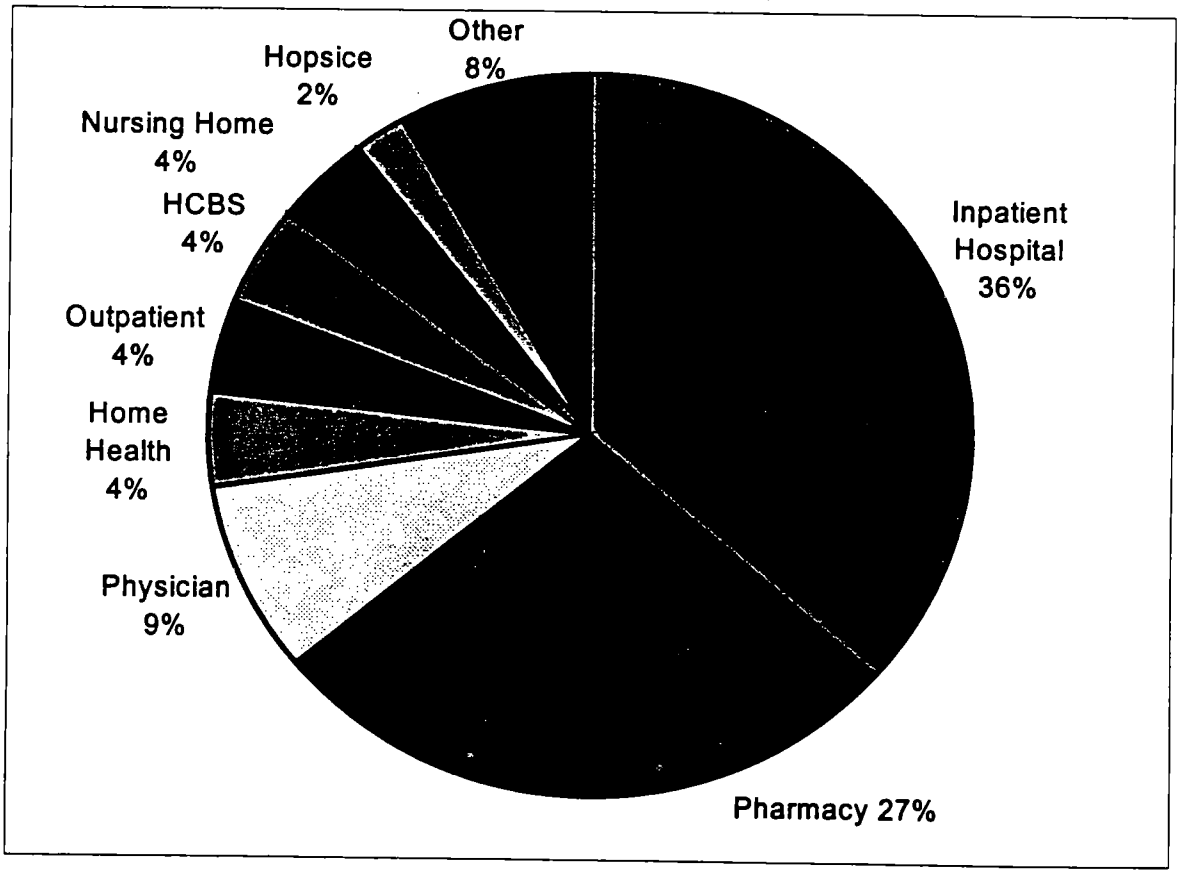
Medicaid SSI-related eligibility requirements dictate that many low-income people with HIV must develop AIDS in order to obtain access to health care services, including new combination drug therapies. Large numbers of persons with HIV must meet, in addition to income and resource requirements, the disability criteria for federal Supplemental Security Income (SSI) program. The Social Security Administration, the federal agency responsible for administration of SSI, uses the CDC's definition of AIDS (CD4+ cell count <200) along with evidence of functional impairment as the threshold for disability determination. Thus many persons with HIV must wait until their health declines to the point that they develop AIDS before they can receive Medicaid, despite the fact that early intervention can improve health and delay the onset of opportunistic infections. Additionally, some persons with AIDS who are receiving health services under Medicaid are attaining a level of functional health that could not have been anticipated prior to the availability of the new drug therapies. For some of these individuals, their conditions have improved to the point where they need few services. However, the services they do continue to need (pharmacy, lab, and physician services) are expensive and not likely to be affordable to this low-income population. The dilemma is that some Medicaid recipients may be in jeopardy of losing Medicaid eligibility, and assistance with drug therapies, as they achieve a higher level of functional health.

Medicaid AIDS-Related Expenditures

Over 26,000 individuals covered under Florida Medicaid received AIDS-related services in fiscal year 1995-96. Medicaid expenditures for this population accounted for roughly $340 million in that fiscal year. Inpatient hospital care represented the service category with the largest cost for this population; comprising just over 36 percent of the total Medicaid expenditures. Prescribed medication, the second largest service category for the group, accounted for

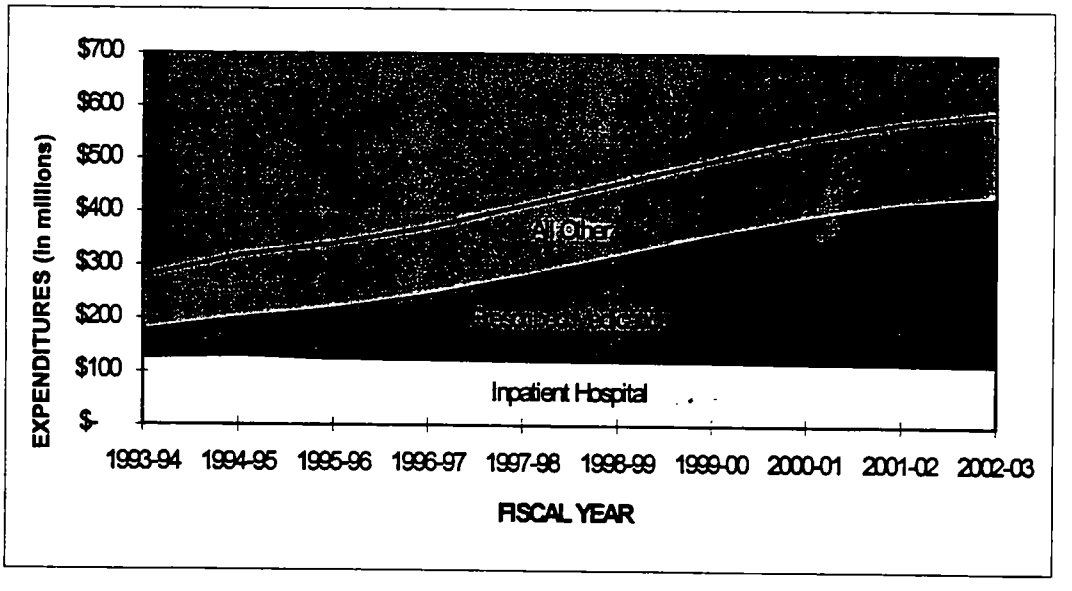
over 27 percent of total Medicaid expenditures. Physician services comprised roughly nine percent of total Medicaid expenditures. Outpatient hospital services and home health care each account for four percent of Medicaid AIDS-related services. Nursing facility payments also account for four percent of expenditures for persons with AIDS/HIV; as does Project AIDS Care (PAC). PAC is a home and community-based services (HCBS) waiver program that provides a broad array of services to individuals with AIDS at risk of hospital or nursing facility placement as an alternative to more costly institutional care.

FIGURE 2: Florida Medicaid AIDS-Related Expenditures, Fiscal Year 1995-96



Florida Medicaid expenditures for persons with HIV/AIDS are projected to reach $600 million by FY 2002-03. The estimate was developed by trending three years of expenditure data extracted from paid Medicaid claims files in FY 1993-94 through 1995-96 to project the cost of HIV/AIDS related services. Expenditures for persons with HIV/AIDS grew an average of 11 percent during this time period. Trends in historical claims data indicate an overall declining rate of inpatient hospital care for persons with HIV/AIDS. The 1997 Florida Legislature authorized the implementation of disease management for Medicaid eligible with AIDS, and reductions in inpatient care are expected to continue over time. Expenditures for prescription medications are increasing at a faster rate than all other Medicaid AIDS-related services. This is a result of new treatment protocols, and a reflection that more individuals are now receiving combination drug therapy earlier in their disease state. Increasing access to combination drug therapy for all Medicaid recipients with AIDS/HIV is expected to account for an increasingly larger share of the overall growth in expenditures.

FIGURE 3: Projected Medicaid HIV/AIDS-Related Expenditures through FY 2002-03



Projections of AIDS-related expenditures are difficult at best due to the ever-changing environment of treating HIV/AIDS. In making national projections of Medicaid expenditures, the Health Care Financing Administration (HCFA) has not incorporated the effect of new drug therapies on AIDS costs, and has indicated that reliable estimates cannot be made at this time.

FEASIBILITY OF AN HIV/AIDS MEDICAID WAIVER

Medicaid waivers allow states to "waive" certain federal Medicaid regulations in order to expand access, improve quality, or contain costs within the Medicaid program. In general, there are two types of Medicaid waivers that can be implemented: 1) program waivers and 2) research and demonstration waivers. Program waivers are usually limited in scope compared to broader research and demonstration waivers. Both are intended to permit flexibility to achieve cost savings in state Medicaid programs. Program waivers are limited in the federal Medicaid regulations that may be waived.

A waiver under Section 1115 of the Social Security Act is the most feasible vehicle for both expanding Medicaid eligibility to a specific targeted population, and limits the available services for which such a population may be eligible. Section 1115 of the Social Security Act allows states to deviate from many standard Medicaid requirements in order to test new ideas of policy merit. In return for greater flexibility, states must commit to a policy experiment that can be formally evaluated. Section 1115 waivers, also called research and demonstration waivers, are being used increasingly by states to enact a broad variety of initiatives, including expanding health care to populations not historically covered under Medicaid. Approved waiver programs range from small-scale pilot projects testing new benefits or financing mechanisms to major restructuring of state Medicaid programs. Demonstration waivers can normally be granted for up to five years at a time. Such authority permits states to try out a far greater range of policies than would otherwise be permissible in ordinary program waivers. For example, under 1115 demonstrations, states may cover new services, offer different service packages or different combinations of services in different parts of the state, test new reimbursement methodologies, and change Medicaid eligibility criteria in order to offer coverage to new or expanded groups. However, 1115 demonstrations must be budget neutral. This means that such initiatives cannot cost more over their duration than the Medicaid program would have spent in the absence of the demonstration.

Demonstration Waiver for Persons with HIV/AIDS

In April 1997, Vice President Al Gore announced that the Clinton Administration had requested that the Health Care Financing Administration (HCFA) explore ways to expand Medicaid eligibility to more low-income persons living with HIV infection. The initiative proposed using Medicaid as a vehicle to ensure that relatively healthy low-income individuals who are HIV+ could afford access to new combination drug therapies. HCFA's initial response to

the Administration's proposed initiative was to develop a solicitation to states for obtaining for Section 1115 demonstration projects to determine if earlier access to Medicaid coverage improves health while reducing health care costs for low income individuals with HIV/AIDS. The demonstration projects would have allowed for a waiver of prior SSI eligibility (i.e. disability determination), and permitted some flexibility for establishing income eligibility criteria at a certain percentage of the Federal Poverty Level. Such demonstrations were to be targeted to individuals in the early stages of HIV disease. The demonstrations would be used to assess whether eligibility for Medicaid in the earlier stages of HIV infection is effective in reducing long term cost to Medicaid for care provided in the later stages of infection.

The requirement for budget neutrality is a critical consideration relative to implementation of a demonstration waiver of expanded health care coverage to HIV-infected persons through Medicaid. Under an 1115 demonstration, Medicaid would be prohibited from spending more than the projected expenditures for AIDS-related services over the proposed waiver period. Statutory requirements limit the approval period of such demonstration projects to five years, and budget neutrality must be demonstrated within this time period. The ability to consider long term Medicaid savings from a more preventative approach to HIV/AIDS care is seriously constrained by the limits of Section 1115 waiver authority. Therefore, significant cost savings, within only a five-year window, would need to be achieved relative to how services are currently provided to persons with HIV/AIDS who are already enrolled in Medicaid.

HCFA studied the potential nationwide costs of providing Medicaid coverage to persons with HIV at four different percentages of the Federal Poverty Level. HCFA has yet to arrive at a budget neutral scenario but has indicated it would continue to explore ways to use the Medicaid program to provide new combination drug therapies to healthier individuals with HIV. The Henry J. Kaiser Family Foundation has also commissioned research to examine the cost implications of Medicaid coverage to persons with HIV prior to their eligibility through disability determination. Florida Medicaid staff participated in a meeting sponsored by the Kaiser Family Foundation in January 1998. Participants included HCFA policy and actuarial staff, researchers and AIDS advocates. While there was a consensus to develop a feasible proposal to expand Medicaid coverage under a budget neutral scenario, considerable divergence remained regarding strategies and cost analysis methodologies for expanding access to Medicaid for low-income persons with HIV.

Costs for HIV/AIDS Expansion under Florida Medicaid

Various scenarios regarding potential eligibility criteria and benefits were examined to determine the potential costs of expanding Florida Medicaid to persons with HIV. The most feasible scenario for achieving budget neutrality under a Medicaid research and demonstration project would include restricting eligibility to low-income individuals at or below 100 percent of the Federal Poverty Level, and limiting available services to only a minimum benefit package. A basic service array consisting of prescription medications, physician services, laboratory services and case management services is considered to be the minimum benefit package. Physician services and lab services were added to the pharmacy benefit because these services are closely linked to prescription medications for HIV/AIDS care. Viral load and CD4+ count testing are critically important in appropriate management of HIV disease, and HCFA has indicated that it will not approve projects that provide coverage for protease inhibitors without viral load monitoring. Case management services were also included to assist in ensuring compliance with complex treatment regimens. The inclusion of additional services was analyzed but found to have an adverse effect on budget neutrality.

To develop a projection of total expenditures, it was necessary to project costs of services for the benefit package and the number of potential new recipients at each level of eligibility. Projected costs for the benefit package were developed for two groups; the HIV+ population (symptomatic and asyptomatic) and the AIDS population. Separate benefit costs for persons with HIV and persons with AIDS are reflective of different level of service needs for these two distinct populations. Examination of FY 1995-96 paid claims data from the Florida Medicaid Management Information System (FMMIS) revealed a large proportion (44 percent) of individuals receiving AIDS-related services that had no hospitalization experience. It was not possible within FMMIS to identify the exact disease state of individuals receiving AIDS-related services. It is assumed that individuals without hospitalization experience are infected with HIV and under treatment, but do not necessarily have full-blown AIDS. (This is consistent with data that approximately 53 percent of the population receiving AIDS-related services are categorically eligible for Medicaid through AFDC criteria. Such individuals need not be disabled to receive Medicaid). The average annual expenditure per recipient for these individuals without hospitalization experience is significantly lower, at $4,062 per year, than the cost of treating individuals further along in the progression of the HIV infection. The average annual cost per recipient for those in Medicaid believed to have AIDS is $20,152. Persons with an AIDS diagnosis are expected to use more services at all levels than HIV+ persons without an AIDS diagnosis. The minimum benefit package is projected to cost $12,280 per individual for the

HIV+ population, and $16,550 per individual for the AIDS population in fiscal year 1998-99. The prescription drug component of the benefit package is estimated to account for $10,721 and $14,096 of the projected annual costs for the HIV (non-AIDS) and AIDS diagnoses populations, respectively. The current costs of combination drug therapies alone range between $8,000 and $10,000 per year.

The second component required to develop cost projections involved estimating the potential population that might be covered under any expansion of Medicaid. There are three key assumptions for the basis of these projections. First, the analysis accepts the Department of Health estimates of the number of persons who have HIV/AIDS in Florida (mid-point of 82,000) and the number of persons with an AIDS diagnosis in Florida (26,800), as of the 1997-98 fiscal year. Additionally, annual growth of the HIV/AIDS population in Florida was projected at six percent. This growth rate was derived from increases in the population from 1994 through 1996 as measured by the Department of Health. Population estimates were made for three distinct sub-populations of persons with HIV/AIDS consisting of asymptomatic HIV infected individuals, symptomatic HIV infected individuals, and persons with AIDS. Estimates of the persons with HIV/AIDS already covered by Medicaid were excluded from the expansion population. Estimates of the number of individuals served through Florida's AIDS Drug Assistance Program (ADAP) were also excluded from the expansion population. This program, administered by the Department of Health, provides medications for low income people with HIV who are not covered under Medicaid, and do not have prescription drug coverage through other means. Also, other factors were included to determine the potential population that would access expanded Medicaid coverage. These factors, included a percentage of individuals aware of their HIV+ status, a percentage of individuals likely to participate in a program of expanded Medicaid eligibility for Medicaid if it were available, and the proportion of HIV infected persons at or below 100 percent of FPL. Income criteria at 150 percent and 200 percent of the Federal Poverty Level were also considered. As might be expected, higher financial eligibility criteria increased the potential cost of Medicaid expansion, and adversely affected budget neutrality. The Section 1115 waiver authority would permit inclusion of a "buy in" process. This process could require higher income individuals served through the expanded Medicaid coverage to contribute toward the cost of care. However, because of the income distribution of Florida's AIDS/HIV population, and the high cost of covered services, this mechanism is likely to provide only minimal reductions in Medicaid program expenditures for expanded coverage.

Even using restrictive Medicaid financial eligibility criteria, it appears unlikely that any broad Medicaid expansion to all HIV infected persons in Florida would

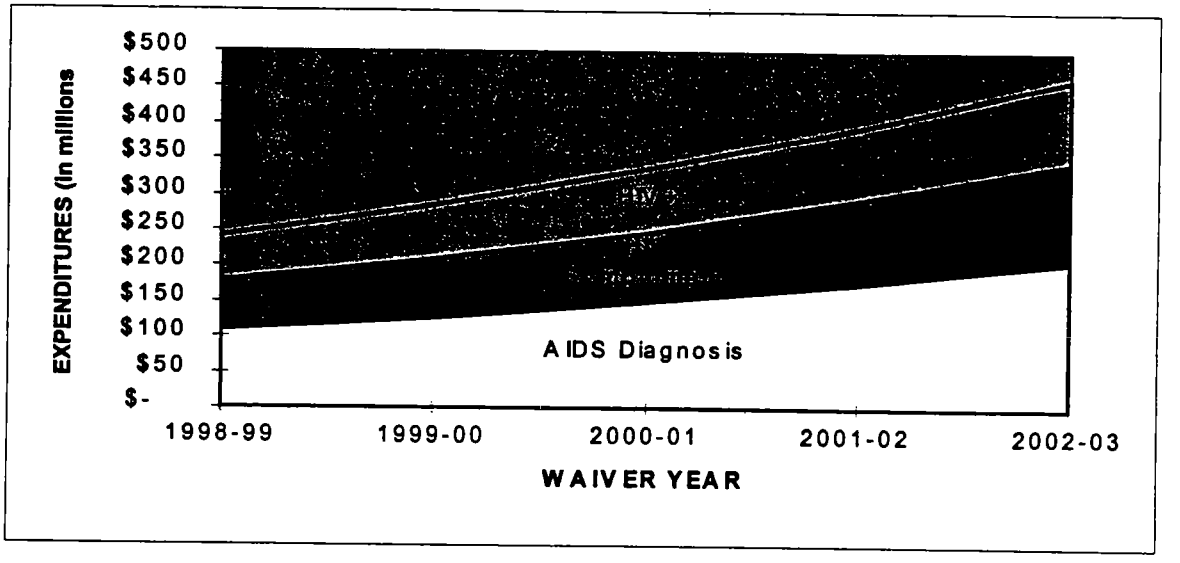
be feasible in a budget neutral environment. Coverage for only a minimum benefit package to all low-income persons with HIV at or below 100 percent of the Federal Poverty Level is projected to cost $1.7 billion over a proposed five-year waiver period. Excluding persons in this income range who were HIV asymptomatic would reduce projected expenditures to nearly $1.3 billion over a five-year demonstration. These scenarios would require an unrealistic degree of cost savings in order to meet the budget neutrality test under an 1115 waiver.

A limited alternative is to provide extended coverage only to persons with AIDS, excluding individuals who are HIV infected but have not yet progresses to a diagnosis of AIDS. This option would extend coverage to individuals with an AIDS diagnosis, but who do not have functional limitations that would qualify for disability determination under SSI. Using 100 percent of the Federal Poverty Level (FPL) as an income threshold, this option would also expand Medicaid eligibility to some disabled individuals who do not meet current Medicaid financial eligibility requirements. The projected five-year cost of providing this more limited expansion is nearly $7.7 million. The financial impact of Medicaid expansion to persons diagnosed with AIDS, who are not yet disabled, could be reduced by lowering the income eligibility threshold below 100 percent of FPL. Establishing income eligibility at 90 percent of FPL, the current income level for Medicaid for the Aged and Disabled (MED-AD), or to near 75 percent of FPL, the current SSI income limit, would further limit the potential costs of Medicaid expansion. However, the lack of available data on the income distribution of persons with AIDS precludes reliable projections of potential expenditures based on these income eligibility thresholds. A restricted expansion, with limiting income eligibility criteria, would move closer to more feasible expenditure targets that might be accomplished in a budget neutral environment. However, restricting expansion to persons with AIDS would not provide earlier access to combination drug therapies for HIV infected individuals who have not yet been diagnosed with AIDS. This would target expanded Medicaid coverage to those most in need of health services, but would continue to leave many persons with HIV without access to basic primary and preventative treatments that may be helpful in slowing the progression of their disease.

It should be noted that any examination of the potential costs of expanded Medicaid coverage is limited. Because of the rapidly changing treatment environment and its effect on future expenditures, cost analysis is difficult at best. Efforts to project populations by disease state, income distribution of persons with HIV/AIDS, and other critical factors are hindered by the lack of solid data available. Cost projections to date have been made based on the best available information. Ultimately, cost projections would need

concurrence from the Health Care Financing Administration before a Medicaid demonstration project could be approved and implemented.

FIGURE 4: Expansion Costs for Persons with HIV At or Below 100 Percent FPL



CONCLUSIONS AND RECOMMENDATION

New treatment guidelines call for a more preventative intervention in the treatment of HIV, often including the use of combination drug therapy from the earliest stage of HIV infection. The new standard of care has tremendous promise for slowing the progression from HIV infection to AIDS. However, the current Medicaid eligibility framework is inconsistent with the new approach to care by requiring many persons infected with HIV to become fully disabled before they are eligible for Medicaid. Additionally, other resources available to HIV-infected individuals who do not currently qualify for Medicaid, such as ADAP, are limited and insufficient to meet the growing demand for combination drug therapies.

States do have the ability to expand Medicaid eligibility under Section 1115 of the Social Security Act. Such expansion may waive certain federal requirements regarding comparability of Medicaid coverage, and target expansion to specific groups of individuals like persons with HIV/AIDS. This authority would also allow for a limited benefit package to be provided to individuals served under the expanded Medicaid coverage. However, federal law allows this innovative experimentation if it can be demonstrated that such expanded coverage will not add to the total Medicaid expenditures. This test for budget neutrality severely limits the potential for expanding access to basic primary care and combination drug therapies to a broad population of persons with HIV. Because of the budget neutrality test, cost savings within projected

Medicaid expenditures would need to be realized in order to finance expanded coverage to persons with HIV not now eligible for Medicaid. A year after the Clinton Administration's proposal to expand Medicaid to persons with HIV, the Health Care Financing Administration continues to analyze the feasibility and potential fiscal impact of Medicaid expansion. Due to the changing environment of HIV/AIDS treatment, and the limited data available, cost analyses are inconclusive at this time. Ultimately, the demonstration of budget neutrality required to implement an 1115 Medicaid waiver must be approved by the Health Care Financing Administration. In light of these considerations it is recommended to the Florida Legislature that:

- **The Agency for Health Care Administration, in conjunction with the Department of Health, should continue to work with officials in the Health Care Financing Administration, and researchers in the academic community to refine cost models, clarify common assumptions, and develop more detailed projections necessary to demonstrate the potential for expanded Medicaid coverage for persons with HIV/AIDS under the condition of Medicaid budget neutrality.**

- **The Agency for Health Care Administration should continue to implement and expand disease management for persons with HIV/AIDS; promote the use of home and community-based services over more costly institutional care; and develop more in-depth analysis of projected cost savings from disease management initiatives that might be available to finance expanded Medicaid coverage to persons with HIV/AIDS.**

As more concrete information on HIV prevalence and new data on Medicaid expenditures becomes available, the cost associated with expanding coverage for persons with HIV should be reexamined. As the Agency for Health Care Administration continues to research the feasibility of a Medicaid waiver to expand eligibility beyond SSI disability requirements, many persons infected with HIV will continue to have limited access to effective treatment that could help to slow the progression of their disease. Approval of a Medicaid research and demonstration process by the Health Care Financing Administration would likely be an involved and lengthy process, further delaying greater access to combination drug therapy for persons with HIV. Therefore, it is recommended that the Florida Legislature authorize the Agency for Health Care Administration to move forward in expanding Medicaid coverage and to seek a Medicaid waiver if cost neutrality can be demonstrated.

Subj: AIDS Activists Renew Medicaid Push
Date: 98-06-26 17:08:11 EDT
From: AOL News
BCC: ShyInDC

AIDS Activists Renew Medicaid Push

.c The Associated Press

By LAURA MECKLER

WASHINGTON (AP) - AIDS activists are renewing their push to get Medicaid to cover expensive drugs for people with HIV after the Supreme Court decision that HIV-infected people are disabled even if they don't show symptoms.

It's one of several ramifications activists see from the precedent-setting case.

``It has broad public health implications - all of them good,'' Daniel Zingale, executive director for AIDS Action, said the day after the court ruled that people infected with HIV are protected by the Americans with Disabilities Act, whether they have symptoms or not.

He and other activists predicted the decision will prevent discrimination on the job and elsewhere, encourage more people to be tested for the virus and help dissipate the prejudice and fear many Americans still harbor about the disease.

``There's still a tremendous amount of discrimination in small towns and rural areas across America,'' said Sandra Thurman, President Clinton's director of AIDS policy.

She agreed that the case may bolster arguments that Medicaid should pay for care for people with HIV, even if they are not poor enough to qualify under normal guidelines.

People with AIDS generally qualify for Medicaid because they are disabled and unable to work. But AIDS-fighting drugs are effective when used before people develop symptoms, and Medicaid does not cover HIV-infected people who are not yet sick.

The Supreme Court's ruling holds no legal sway over the Medicaid program. It ruled that HIV was a disability for civil rights purposes of preventing discrimination but has no effect on a different section of law dealing with disability benefits.

Still, AIDS Action argues that the high court has ``altered the landscape'' of the debate.

``If the Supreme Court says people with HIV should be protected from discrimination, then logic and morality dictate that protecting them from developing AIDS is just as important,'' Zingale wrote in a letter Thursday to Medicaid's chief administrator.

Sen. Robert Torricelli, D-N.J., wrote a similar letter Friday to Health and Human Services Secretary Donna Shalala.

The Clinton administration has said it would like to extend Medicaid coverage to people with HIV, but it is too expensive - $3 billion to $9 billion over five years.

HHS spokesman Chris Peacock said Friday that the administration has not given up. ``We're committed to trying to find a way to expand Medicaid,'' he said, though he did not offer any specifics.

AIDS activists are also hoping the court decision will encourage people to get tested for the HIV virus without fear of discrimination.

About a half-million people are infected with HIV, but do not yet show symptoms of AIDS. Half of them don't know that they are HIV-positive.

A variety of reasons keep people from being tested, activists explain, including fear of discrimination.

``Even in 1998, HIV is still a very stigmatized condition,'' said Bennett Klein, an attorney with the Boston-based Gay & Lesbian Advocates & Defenders, who represented Sidney Abbott, the HIV-positive woman who sued her dentist when he

refused to fill a cavity.

``We want people to get tested and find out their HIV status as early as possible," Thurman said. ``There are now treatments available."

Bill Barnes, 21, found out he was HIV positive through an anonymous testing center in New York City when he was 15.

``That way, no one could track it back to me," said Barnes, who now works on AIDS policy for San Francisco Mayor Willie Brown. ``Everybody's fearful if you test positive, people will find out before you're ready to tell them."

While there's no way to prove it, activists also hope the Supreme Court decision will help Americans to break down their own fears and prejudices surrounding people with HIV.

``It forces people to recognize that individuals with HIV and AIDS deserve to be treated with fairness and equality," said Chai Feldblum, a Georgetown University professor who filed a brief on behalf of activists in the court case. ``That sets a tone in terms of how the country deals with this disease."

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Subj: Help for AIDS Patients Moves Slowly
Date: 98-06-26 16:20:29 EDT
From: AOL News
BCC: ShyInDC

Help for AIDS Patients Moves Slowly

.c The Associated Press

By ALEXANDER G. HIGGINS

GENEVA (AP) - Only 5 percent of people living with the AIDS virus - those in Western Europe and North America - are reaping the full benefits of the dramatic advances in treatment, a leader of the World AIDS Conference says.

Of the 30.6 million people infected with the virus worldwide, only about 1.3 million can afford and obtain the new drug combinations that have proved so effective in combating it, conference chairman Dr. Bernard Hirschel said.

The conference, which opens Sunday, will bring together 12,000 of the world's top experts in the global campaign against AIDS. Convening for the first time in 2 1/2 years, it has set the challenge of finding low-cost ways to stop the spread of AIDS and help people afflicted with it in Africa, Asia and Latin America.

Hirschel and other experts say there is hope because many measures do not require expensive technology, among them preaching the need to practice safe sex.

The conference will review 5,000 reports on research around the world, from laboratory advances to work with prostitutes in Africa. It will look at the new drug combinations that have slowed the progress of the disease in Europe and North America, review new combinations in the pipeline and consider what can be done to reduce their cost.

Robin Gorna, executive director of the Australian Federation of AIDS organizations and a conference organizer, said another problem with current treatment is it is complicated.

``We need simpler treatment, ever more effective, easier to take with fewer side effects," Gorna said.

Several major drug companies are planning to announce at the conference that they will cut their prices on AIDS drugs by 75 percent to developing countries, a U.N. official said this week in New York.

Still, most of the latest drugs remain out-of-reach for many people with HIV, experts said, adding that researchers are looking at whether lower-cost products, such as vitamins, offer any hope.

Some reports are also expected on the development of vaccines, with scientists turning toward human testing.

One report will look at why some prostitutes in Africa have shown immunity to the disease and what that means for finding ways to help others. Others will consider developments in male or female condoms that can help women protect themselves.

Another major area of research is preventing transmission of AIDS from mothers to babies, not only during birth but also through breast milk.

UNAIDS, the Joint United Nations Program on HIV/AIDS, noted in a report this week that HIV-infected women in industrialized countries largely stopped breast feeding when research showed the virus can be transmitted in breast milk.

But in the developing world, where many mothers may not know they are HIV positive since testing is unavailable, it is difficult to enforce.

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Subj: 12th World AIDS Conference Report
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12th World AIDS Conference Report

Researchers Focus on Powerful AIDS Treatments With Fewer Pills and

Simpler Regimens

GENEVA, June 29 /PRNewswire/ -- Several studies being presented during this week's 12th World AIDS Conference show that twice daily anti-HIV regimens including Viramune(R) (nevirapine), a potent non-nucleoside reverse transcriptase inhibitor (NNRTI), achieve undetectable levels of the HIV virus in the blood while increasing infection-fighting immune cells. Unlike several other anti-HIV drugs, which can require as many as 18 pills per day, Viramune only requires one 200 mg tablet twice-daily.

"Although more anti-HIV agents are available than ever before, resistance remains a problem. Because inability to adhere to treatment is often a cause of resistance, we're continually looking for highly effective therapies that also are easy for patients to take," said Dr. Francois Raffi, Professor at the Centre Hospitalier Regional et Universitaire de Nantes. "Viramune is an obvious choice because it rapidly suppresses the HIV virus, and is taken twice a day with or without food." Viramune is generally well tolerated. Its most common side effect is rash.

Undetectable Viral Loads Achieved With Only Seven-to-Eight Tablets Per Day

Dr. Raffi will present data which indicates that starting anti-HIV therapy with Viramune, d4T (Zerit(R), stavudine) and ddI (Videx(R), didanosine) dramatically reduces virus in the blood to undetectable levels. This treatment combination is a twice-daily regimen requiring from seven to eight pills per day and has no cross resistance with protease inhibitors, thereby preserving future treatment strategies with these agents. Sixty two percent (24/39) of patients taking Viramune in combination with ddI and d4T, currently at week four of the study, have achieved undetectable levels (<500 copies/ml) of HIV in the blood. Additionally, 85% (17/20) of patients at week 16 of the study have achieved undetectable viral load. The mean viral load reduction from baseline (4.6 log10 copies/ml) was 1.9 logs at four weeks and at 16 weeks. Mean CD4+ increase from baseline (429 cells/ml) was 118 cells/ml and 158 cells/ml respectively.

Simple Regimen Effective in Treatment Naive and Experienced Patients

Data on Viramune, d4T and ddI in both patients taking anti-HIV drugs for the first time, and patients who needed to stop protease inhibitor therapy due to adherence issues or intolerance will be presented by Dr. Cathy Pell of Taylor Square Private Clinic in Sydney, Australia. One hundred percent (8/8) of patients with no prior treatment achieved viral loads below the limit of detection (<400 copies Roche Amplicor assay); 75 percent of these patients maintained undetectable viral loads for the 26-week follow-up period. A total of 39 patients switched from protease inhibitor therapy. Of these, 24 had detectable viral load at baseline and 15 had undetectable viral load at baseline. In the baseline-detectable group, 54% (13/24) achieved undetectable viral load during the 26-week period. Of the 10 evaluable patients in the baseline-undetectable group at 26 weeks, 70% remained undetectable.

"For patients experiencing difficulties with protease inhibitors, changing to this more convenient, but still effective regimen of Viramune, d4T and ddI is a very attractive option," remarked Dr. Pell. "This regimen also is highly effective for patients taking anti-HIV therapy for the first time."

At 26 weeks, mean reduction in viral load was 2.16 log10 from baseline (5.10 log10 copies/ml) for the treatment-naive group and 2.02 log10 from baseline (3.56 log10 copies/ml) for the PI-experienced group. The mean increase in CD4+ cells from baseline (286 cells/ml) for the naive group was 137 cells/ml and 74 cells/ml from baseline (367 cells/ml) for the PI-experienced group.

Further evidence supporting the potency of non-protease inhibitor combinations containing Viramune is the INCAS Trial in which Dr. Julio Montaner's research team demonstrates continuing viral suppression and stabilized CD4+ cells for almost three years in patients taking Viramune, ddI and AZT (Retrovir(R), zidovudine). Data being presented at the conference indicate that at 33 months, 67% (6/9) of patients continuing on the triple regimen in the extension trial have maintained viral load below limits of detection (<20 copies/ml) and have a more elevated CD4+ count from baseline than the double therapy groups studied.

Viramune is indicated for use in combination with other antiretroviral agents for the treatment of HIV-1 infection. This indication is based on analysis of changes in surrogate end-points. At present, there are no results from controlled clinical trials evaluating the effect of Viramune in combination with other antiretroviral agents on the clinical progression of HIV-1 infection, such as the incidence of opportunistic infections or survival. Viramune is generally well tolerated. The most commonly reported adverse events associated with Viramune are rash, fever, nausea, headache and abnormal liver function tests. Severe and life-threatening skin reactions (Stevens-Johnson Syndrome, Toxic Epidermal Necrolysis), including fatal cases, have occurred in patients treated with Viramune. Viramune(R) (nevirapine) is a product of original research done at Boehringer Ingelheim Pharmaceuticals, Inc., a member of the Boehringer Ingelheim group of companies. Viramune is marketed in the United States by Roxane Laboratories, a member of The Boehringer Ingelheim Group of companies.

SOURCE Boehringer Ingelheim

CO: Boehringer Ingelheim

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Subj: New Drugs Reduce AIDS `Cocktail'
Date: 98-06-29 14:11:27 EDT
From: AOL News
BCC: Tsummers

New Drugs Reduce AIDS `Cocktail'

.c The Associated Press

By DANIEL Q. HANEY

AP Medical Editor

GENEVA (AP) - Two new medicines are as effective as the breakthrough drugs that revolutionized AIDS care - and they cut the daunting number of pills patients must take each day by two-thirds.

The drugs, described Monday at the 12th World AIDS Conference, may become important alternatives to protease inhibitors, the key ingredient of the three-drug cocktails that are now standard AIDS therapy.

Protease inhibitors combined with two older drugs became routine treatment two years ago. Taken early in infection, the combination keeps people from getting sick. When given to people whose bodies are already ravaged by the HIV virus that causes AIDS, the treatment often produces dramatic turnarounds.

The drugs do not work for some people, however, and others can't take them because of side effects. In addition, the treatments require taking up to 20 pills a day at precise times.

Indeed, the difficulty of using these medicines has been one of their chief drawbacks. Doctors have been reluctant to prescribe them to people who are not motivated to take them exactly on schedule, because missing even a few pills allows mutant viruses to evolve that are impervious to the drugs.

Doctors say the two new drugs - DuPont Pharmaceuticals' Sustiva and Glaxo Wellcome's Ziagen - could help make lifesaving treatment more widely available. Sustiva is known generically as efavirenz and Ziagen as abacavir.

Both companies have asked the U.S. Food and Drug Administration for approval to sell the drugs, based on the data presented at this week's meeting, the largest gathering yet on the AIDS virus.

When taking protease inhibitors, ``you have to plan, you have to be organized, and you have to be disciplined,'' said Dr. Schlomo Staszewski of Goethe University in Frankfurt, Germany, who was involved in testing both new drugs.

``There is a need for simpler treatments, ones that patients can adhere to better.''

Patients on three-drug combinations with Sustiva would take five pills a day: one in the morning and four in the evening. Those on Ziagen would take three in the morning and three in the evening.

The two drugs have not been compared head to head. Only Sustiva has been directly compared to standard protease inhibitor therapy.

``Sustiva is particularly interesting because this is the first time that a protease-free regimen looks comparable,'' said Dr. Douglas Richman of the University of California, San Diego.

He said Sustiva also appears to work better than Ziagen in patients who already have received other AIDS drugs, although both will probably be useful new medicines.

In the Sustiva study, 450 HIV-infected people were randomly assigned to take either Sustiva or Crixivan, a standard protease inhibitor. Both groups also got AZT and 3TC, which are older standard AIDS drugs. After 24 weeks, virus levels in 69 percent of the Sustiva patients fell below the amount detectable with standard tests, compared with 52 percent on the protease inhibitor.

In the study of Ziagen, doctors treated 173 people. Half got Ziagen plus AZT and 3TC, while the rest took AZT and 3TC alone. After 16 weeks, virus levels fell to undetectable levels in 75 percent on Ziagen, compared with 35 percent in the

people on the two-drug combination.

``This opens up new treatment strategies for both physicians and patients," said Dr. Margaret Fischl of the University of Miami, who directed the Ziagen study.

Both Sustiva and Ziagen thwart HIV by blocking an essential enzyme called reverse transcriptase, which the virus needs to take over cells and produce new copies of itself.

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Subj: Satcher Says U.S. Must Address AIDS
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Satcher Says U.S. Must Address AIDS

.c The Associated Press

By GEIR MOULSON

GENEVA (AP) - The United States must be more straightforward about AIDS with its young people, Surgeon General David Satcher told the largest-ever AIDS conference Monday.

``In a country where sex is happening everywhere - movies, TV, everywhere you can imagine - when it comes to addressing it, frankly we have some way to go," Satcher told a session on youth prevention programs at the 12th World AIDS Congress.

Satcher, the U.S. government's top doctor, said the United States needs to deal with AIDS in a realistic way, not just stress the need for abstinence.

He called for televised condom commercials and deplored the ban on federal funding of needle exchanges for drug users. In April, Republicans in the House of Representatives pushed through legislation that would bar such funding.

Satcher said an estimated 40,000-80,000 people in the United States, mostly adolescents, become infected each year with HIV, the virus that causes AIDS.

One in four sexually active U.S. teen-agers contracts a sexually transmitted disease each year, according to researcher Stephen W. Banspach of the Centers for Disease Control in Atlanta.

Banspach helped conduct a three-year study in Texas and California that showed safe-sex education increased the use of condoms among high school students without encouraging sexual activity.

Satcher joined experts from other countries calling for more efforts to prevent the spread of HIV.

Feliciano Reyna of RedMet SIDA, a group of AIDS organizations in Caracas, Venezuela, called Venezuela ``a country where silence rules," blaming the government and the Roman Catholic Church for not talking about AIDS.

Christo Greyling of South Africa stressed the need to tailor prevention programs to individual cultures.

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Subj: Doctors Raise Hope of Stopping AIDS
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Doctors Raise Hope of Stopping AIDS

.c The Associated Press

By DANIEL Q. HANEY

AP Medical Editor

GENEVA (AP) - Researchers raised the possibility today that treatment may someday eliminate the AIDS virus from the body or lower it to a point where the immune system can successfully control it.

``Eradication of HIV is not a myth," said Dr. Roberto Siliciano of Johns Hopkins University. ``This is something we can do."

The goal, he said, is to find the spots in the body where virus lingers, then flush it out and kill it.

Siliciano spoke today at the 12th World AIDS Conference, where researchers reported on experiments to measure long-lived pools of HIV-infected cells and destroy them.

Combination drug therapies with medicines called protease inhibitors can reduce levels of the HIV virus in the bloodstream so low that they cannot be readily measured. However, tests show that so-called memory CD4 cells in the lymph tissues continue to harbor the virus.

After a person has spent years on anti-AIDS treatment, the immune responses that have been damaged by AIDS rebound and grow more powerful. Some scientists believe at this point it may sometimes be possible for the immune system to control the lingering infection even if the virus is not wiped out entirely.

``It may be that you don't have to eliminate it," said Dr. Anthony Fauci of the U.S. National Institute of Allergy and Infectious Diseases.

He and others at the meeting described cases in which people stopped treatment and yet their virus did not rebound in the bloodstream, apparently because their immune systems were able to control it.

Fauci said one possibility is to stimulate the latently infected cells so they will release their virus and die. While experiments show this may shrink the pool of infected cells, so far it has not wiped them out completely.

At the conference on Monday, researchers described the development of two new medicines that may offer easy-to-take alternatives to protease inhibitors, which have been the key ingredient of the so-called AIDS cocktail until now.

The medicines both appear to be about as effective as protease inhibitors but require taking far fewer pills than the standard mix. They may help those people who fail to respond to protease inhibitors or suffer bad side effects from them.

The two drugs are DuPont Pharmaceuticals' Sustiva and Glaxo Wellcome's Ziagen. Sustiva is known generically as efavirenz and Ziagen as abacavir. Both companies have asked the U.S. Food and Drug Administration for approval to sell the drugs, based on the data presented at this week's meeting.

The drugs will be given in combination with two older AIDS medicines, like protease inhibitors. Taken early in infection, the protease inhibitor combinations keep people from getting sick. When given to people whose bodies are already ravaged by the virus, they often produce dramatic turnarounds.

Their biggest drawback for many is taking as many as 20 pills on a precise schedule throughout the day. Some doctors are reluctant to prescribe them to people who are not motivated to take them exactly on schedule, because missing even a few pills allows mutant viruses to evolve that are impervious to the drugs.

When taking protease inhibitors, ``you have to plan, you have to be organized, and you have to be disciplined. There is a need for simpler treatments, ones that patients can adhere to better," said Dr. Schlomo Staszewski of Goethe University

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