Peter P. Swire
05/24/99 07:19:40 PM

Record Type: Record

To: See the distribution list at the bottom of this message

cc: Devorah R. Adler/OPD/EOP@EOP, Donald R. Arbuckle/OMB/EOP@EOP, Amy Squires/OMB/EOP@EOP, Joshua Gotbaum/OMB/EOP@EOP

Subject: law enforcement and action tonight/early a.m.

I just got the note that the 7:30 p.m. conference call was cancelled. Here is an action issue for ASAP on law enforcement.

I have been talking to people from the privacy community, including Jan Lori Goldman. Strong sentiment -- an excellent day and past couple of days, with important progress. Overall, say the advocates,

Biggest complaint is law enforcement, and especially the "exigent circumstances" language. At the hearing a couple of weeks ago, reports Jan Lori, Bentivoglio said that *current practice* in the "rapist's hand stuck in the car door" example is to ask hospitals for people fitting the profile, and then get a warrant or court order to identify the individual. The bill, by contrast, would allow access without any compulsory process.

Paul Harrington, the staff director for Jeffords, said to Jan Lori this afternoon: if we get a letter from Justice acquiescing in this, we will delete the exigent circumstances language from the bill. Such a letter would have to go *tonight*(or perhaps very, very early in the morning). I hope we can consider having such a letter go.

Arguments for cutting the exigent circumstances language:

(1) Current practice in the rapist case, as testified to at the hearing, is to get compulsory process (Bentivoglio's later "10 rapists so no probable cause" was not raised at the hearing, is questionable as a matter of law, and extends the hypothetical to highly improbably facts);

(2) No legislative history on "exigent circumstances" and the language is not nearly so well defined as "hot pursuit", especially in the new land of health privacy practices; privacy advocates have a plausible claim that we are opening a large loophole to law enforcement access;

(3) This is the key moment for the Administration not to still be less protective of privacy than everyone else -- action on this issue now will frame how the issue is treated in the rest of the legislative process.

Arguments for keeping the exigent circumstances language:

(1) The arguments favoring the Administration's previous position on law enforcement access;

(2) The district attorneys' lobbyist is apparently strongly supporting the exigent circumstances language.

Message Sent To:

Sally Katzen/OPD/EOP@EOP
David W. Beier/OVP@OVP
Christopher C. Jennings/OPD/EOP@EOP
Daniel N. Mendelson/OMB/EOP@EOP
Mark E. Miller/OMB/EOP@EOP

OFFICE OF MANAGEMENT AND BUDGET

Legislative Reference Division

Labor-Welfare-Personnel Branch

Telecopier Transmittal Sheet

URGENT

FROM: Bob Pellicci -- 395-4871

DATE: 5/20 **TIME:** 4 35 p.m.

Pages sent (including transmittal sheet): 10

COMMENTS: OASIS revisions per Dan, Peter Swire & Health Division - Need your okay/comments no later than 10 am tomorrow, May 21st. Thanks.

TO: Chris / Devorah

PLEASE CALL THE PERSON(S) NAMED ABOVE FOR IMMEDIATE PICK-UP.

REVISED 05/21/99

DRAFT TESTIMONY
JEFF KANG, M.D., DIRECTOR
OFFICE OF CLINICAL STANDARDS AND QUALITY
HEALTH CARE FINANCING ADMINISTRATION
on the
HOME HEALTH CARE
OUTCOME & ASSESSMENT INFORMATION SET (OASIS)
before the
SENATE SELECT COMMITTEE ON AGING
MAY 24, 1999

Chairman Grassley, Senator Breaux, distinguished committee members, thank you for inviting us to discuss our efforts to improve home health care quality through better patient assessment and measurement of the outcomes of care. We are required by law to survey the quality of home health care with a "standardized, reproducible" assessment instrument. To improve care and comply with the law, we will be using the Outcome and Assessment Information Set (OASIS).

OASIS helps home health agencies determine what patients need, develop the right plan for their care, assess that care over the course of treatment, and learn how to improve the quality of that care. It incorporates all the information about patients' health and functional status, health service use, living conditions, and social support that are needed to support all the home health agencies' responsibilities. **In addition to monitoring quality,** OASIS also is essential for accurate payment under the new home health prospective payment system that the law requires us to use beginning October 1, 2000. We will be requiring use of OASIS by home health agencies as a Condition of Participation in the Medicare and Medicaid programs this year.

The important benefits of OASIS must be implemented in a way that protects personal privacy. At HCFA, we have an excellent historical record of safeguarding sensitive beneficiary information. Our agency provides greater protection for personal medical information than generally exists in the private sector, and we are actively participating in the

Administration's inter-agency process to make Secretary Shalala's recommendations for medical privacy work on the operational level.

In recent months, we have come to realize that stronger privacy protections must be built into the structure of our new operations. President Clinton and Vice President Gore have both spoken about the paramount importance they attach to medical records privacy. This is why the Administration has been a consistent advocate for effective medical records privacy legislation. I am pleased to announce some new steps we are taking to assure the privacy of patients while maintaining the legitimate focus of the OASIS program, such as:

- **Careful drafting of a notice that Medicare and Medicaid patients will receive. The notice will explain why OASIS data is collected, and inform patients of their right to see and request corrections of the data.**

- **Limitations on "routine uses" of data under the Privacy Act, so that personally identifiable data will only be used where statistical information is not sufficient. Among other changes, personally identifiable data will no longer go to accrediting organizations such as the Joint Commission for Accreditation of Health Organizations.**

- **Major changes in the treatment of private-pay patients under OASIS. We have decided that information on non-Medicare and non-Medicaid patients will *not* be transmitted to the states or the agency in personally identifiable form.**

- **Acceleration of efforts to encrypt data during transmission, to provide yet another level of protection. Note: David Beier asked whether anything can be said about deadlines or goals for implementation of this.**

~~We have taken several steps to address privacy concerns raised by Vice President Gore and others. No Administration has been more committed to protecting medical privacy. Our agency has a solid track record of consistently safeguarding sensitive beneficiary information. In fact, we provide much greater protection for such information than is afforded in the private sector. For OASIS data, we are providing even more security beyond our usual, stringent protections.~~

- ~~We will explicitly notify Medicare and Medicaid patients of:~~
  - ~~why OASIS data is collected;~~
  - ~~their right to see, copy, and request corrections of the data;~~
  - ~~their right to confidentiality and the specific Privacy Act rules which apply; and~~
  - ~~their right to not answer OASIS questions.~~
- ~~We will have home health agencies remove OASIS data on patient financial factors before reporting it to Medicare and Medicaid.~~
- ~~We will have home health agencies remove all information that could potentially identify individuals who are not enrolled in Medicare or Medicaid.~~
- ~~And we are accelerating efforts to encrypt data to provide yet another layer of protection.~~

We are also making special efforts to help home health agencies learn how to use this valuable tool. Research conducted by the University of Colorado shows that it takes home health care professionals about eight patient assessments to become proficient in using OASIS.

Once past that learning curve, OASIS actually slightly reduces the total time it takes to conduct a thorough patient assessment. Home health care professionals who have used OASIS in demonstration projects agree that it takes no longer to use than their previous assessment methods. However, because OASIS is structured in a checklist format, home health staff using it spend less of the total evaluation time writing out a narrative of their assessment findings and more time with the patient.

Efforts to help providers through the OASIS learning curve include:

- a satellite broadcast training session on August 20, 1998 to XX sites across the country reaching ?30,000? home health care professionals (tapes of this session are also available);
- numerous presentations at industry trade association meetings;
- distribution of a free, detailed manual on how to collect OASIS data, use the software, and report the data;
- manuals, software, updates, and other additional assistance that can be downloaded from the Internet at *hcfa.gov*, and *hcfa.gov/medicare/hsqb/oasis/oasishmp.htm*;
- answers to questions on installing OASIS software via a toll-free telephone line at 1-877-201-4721 and via E-mail *haven help@ifmc.org*;
- establishing OASIS Educational Coordinators in all States;
- a week long conference last September to teach State personnel about OASIS; and
- a "train the trainer" program last October for all State OASIS Educational Coordinators to provide materials and detailed information on how to teach home health care professionals in their State how to use OASIS.

Background

Home health patients are among the most vulnerable Medicare and Medicaid beneficiaries. They tend to have more health problems, and the fact that care is delivered in the home makes monitoring the quality of that care more challenging. The Omnibus Budget Reconciliation Act of 1987 mandated that Medicare survey the quality of home health care and services with a "standardized, reproducible" assessment instrument. The following year we contracted with University of Colorado researchers and clinicians to develop such an instrument. We have been working ever since to refine and validate what has become OASIS.

OASIS provides a standardized format for the patient assessments that home health agencies have been doing all along. It does not require additional effort for agencies that have been conducting the

thorough patient assessments that are needed in order to provide appropriate care. OASIS incorporates only information needed to support concrete indicators of patient need and quality of care. ~~For example, it records whether a patient is depressed in order to track progress in treating that depression.~~ **[delete or choose a less controversial example]**

The 79 data elements in OASIS were developed by clinicians and are valid, reliable, and risk adjusted, taking into account all characteristics of patient populations. This ensures that assessments done by different health care professionals with OASIS consistently yield the same results. It also ensures that quality measurement takes into account whether agencies are caring for ~~low income or~~ sicker patients and therefore might have what otherwise would appear to be poorer care or outcomes.

OASIS has been used by 162 home health agencies in various demonstration projects around the country. It has been tested in a national Outcome-Based Quality Improvement demonstration involving 50 home health agencies of all sizes, and in a single-State demonstration project involving 22 agencies. A slightly abbreviated form of the OASIS has been used for quality improvement purposes in the national Medicare prospective payment demonstration, which includes 90 agencies in five States. **[Include brief argument as to why abbreviated data set was inadequate]**

OASIS is supported by the American Academy of Home Care Physicians, the National Alliance for the Mentally Ill, and many home health care providers who are voluntarily using OASIS because of its unprecedented value in promoting high quality care and comprehensive, accurate, clinical record-keeping. Home health care professionals using OASIS report that it is helping them to be ~~more~~ focused on the needs of ~~individual~~ patients, and to provide better care in fewer visits and with fewer subsequent hospitalizations.

Implementation

How best can we advocate?

We first published a proposed rule for requiring use of OASIS by all home health agencies participating in the Medicare and Medicaid program in the *Federal Register* on March 10, 1997. Many comments on the proposed regulation suggested adding additional questions. However, to keep OASIS at a reasonable length, we instead will allow agencies flexibility to **expand** ~~tailor~~ OASIS ~~to~~ **for** their own patient population. For example, an agency that provides a larger share of mental health services can add extra questions related to mental health if it so chooses; **however, these data will not be transmitted.**

On January 25, 1999, we published a final regulation requiring use of OASIS and an interim final rule requiring that home health agencies encode and transmit the data to us. We had planned for home health agencies to begin mandatory reporting of OASIS data on April 26, 1999. However, on April 7 we announced that we would postpone the requirement in order to conduct a thorough evaluation of privacy concerns **and to complete the review of OASIS pursuant to the Paperwork Reduction Act of 1995.** ~~With those~~ **Once these** concerns ~~now~~ **are** addressed, we expect to publish a new date for the start of mandatory collection and ~~reporting~~ **will report it** in the *Federal Register*. ~~soon.~~

Once reporting begins, home health agencies will transmit computerized, coded OASIS data to State survey agencies using a private network with a direct phone connection. The State will compile the data and send it to the Health Care Financing Administration. OASIS system users must enter an ID and password at three different checkpoints before access is permitted. And, ~~at every step in the process,~~ the data **transmitted to the States and to HCFA** is fully protected under the federal Privacy Act. The Privacy Act has been effective in ensuring confidentiality of Medicare data.

We will develop a performance report for each home health agency based on its OASIS reports, including a comparison of its performance to the State and national average, ~~That~~ which will allow home health agencies to identify their own weaknesses and improve the quality of care they provide. It also will allow us to compare the quality of care among agencies and thereby increase scrutiny for those that

need more oversight and assistance in improving quality. Eventually, we will share results with the public so consumers can make informed choices among home health agencies based on the quality of care they provide.

Data that can identify individual Medicare and Medicaid patients are critical to ensuring that we pay accurately for care and that we can monitor the quality of care. It allows evaluators to assess whether a home health patient's later admission to a hospital or nursing home might be related to gaps or problems with the care provided by the home health agency and identify potential areas for improvement. It is also essential **for ensuring accurate payment under the prospective payment system. In particular it links the OASIS data to actual claims data in order to create the proper weightings for reimbursement.**

As I stated earlier, all information that could be used to identify private pay patients will be removed by the home health agencies before OASIS data is reported **to HCFA and the State.**~~, and we will not require agencies to report data on private pay patients until systems for removing identifiable information are in place~~.

~~Data on private patients is collected in order to ensure consistent quality of care for all patients. It allows us to compare care provided to private pay and Medicare patients and make sure that incentives under the prospective payment system to provide care efficiently are not limiting appropriate care for Medicare patients. Collecting data on all patients, regardless of payer, is standard for all Medicare and Medicaid Conditions of Participation for home health agencies, as well as for Conditions of Participation for hospitals and other providers, and for quality assessments by private health care accreditation bodies, such as the Joint Commission on Accreditation of Health Care Organizations.~~

OASIS and Prospective Payment

OASIS data are critical to development, implementation, and accurate payment under the home health prospective payment system that Congress has required we implement in October 2000. We need to collect OASIS data as soon as possible in order to develop prospective payment rates and estimate their impact based on comprehensive national data. Doing so based on the limited OASIS research data available to us now could jeopardize our ability to pay accurately and to understand in advance how different types of agencies across the country will be affected.

The comprehensive information in OASIS is **necessary to** accurately determine the appropriate amount of care, and therefore the appropriate amount of payment for that care. **This is particularly important in the home health environment, which is complicated by confounding factors such as patient behavior.** Patient diagnosis alone, which is the basis for inpatient hospital prospective payment, predicts less than 10 percent of home health patients' need for service.

Using OASIS to both determine accurate payment and assess quality helps to minimize the burden on home health agencies. It also helps fight fraud and abuse, which has been a substantial problem in home health care, because it balances incentives. While prospective payment creates an incentive to "upcode" and say patients are sicker in order to receive higher payment, doing so with OASIS would result in poor quality indicators. That could trigger an investigation, as well as result in a competitive disadvantage when OASIS data are eventually shared with the public.

Using OASIS to monitor quality is even more essential under a prospective payment system. As mentioned above, prospective payment creates highly effective incentives to provide care efficiently, but those incentives must not be allowed to reduce appropriate care. OASIS will help providers accurately assess what the proper level of care is, and it will help us monitor that care to ensure that patients are getting all the care they need.

CONCLUSION

OASIS represents a significant advance in home health care. It is proven in rigorous testing to help improve the quality of patient care and the outcomes of that care. It allows home health care professionals to spend more time with patients and less time writing up assessments. It will help ensure accurate payment under the new prospective payment system. It will help ensure that beneficiaries receive high quality care. And it will help protect taxpayer dollars and the integrity of the Medicare and Medicaid programs. We are taking extra precautions, beyond our already stringent privacy protections for Medicare and Medicaid data, to ensure the confidentiality of OASIS information, **and we are communicating these precautions to all (Medicare, Medicaid, and private pay) patients before they receive home health care. In addition,** ~~And~~ we **are** working to help home health care professionals learn how to use this important new clinical advance. I thank you for holding this hearing, and I am happy to answer your questions.

# # #

THE WHITE HOUSE

WASHINGTON

MEMORANDUM

chris/ start see me on this JOHN

TO: John Podesta
Gene Sperling
Bruce Reed

FROM: Chris Jennings
Sally Katzen

CC: Karen Tramontano

DATE: May 17, 1999

RE: Medical Privacy Legislation

We wanted to give you a heads up that the medical privacy issue will be heating up.

As you know, Congress has until August 21st to make significant headway towards the enactment of legislation; if it doesn't, then HHS gets a green light to issue regulations. The President has recently re-committed to this in both the State of the Union and at the Consumer Financial event two weeks ago.

Beginning with the Senate Labor Committee markup on May 25th, the Congress is now sorting through / marking-up a number of privacy bills, putting us in the position of having to react to a wide variety of proposals with several tough issues. Attached is a brief description of four of the major issues. We will know in a few weeks if Congress can make significant progress on legislation by August; if it doesn't, we will face many of the same issues in the regulatory process.

The last time serious thought was given to medical privacy issues was two years ago, and a lot has changed. There is considerable interest in this topic in OVP, among Congressional Democrats, and the elite media. We are launching an interagency process to sort through the major issues, and will keep you advised.

As we reengage in this process, we would like to ask your opinion as to how to proceed on the issue of law enforcement access to medical records. The position we articulated two years ago, which does not impose any new constraints on the ability of law enforcement officials to access to medical records, is extremely controversial and has been criticized by advocates, members of Congress, and the media. This Administration position is less protective of medical records privacy than all of the legislative proposals currently being debated, including the legislation

proposed by Senator Bennett, who represents the most conservative position on this issue.

At a recent hearing in front of the Senate Labor Committee, Senators from both sides of the aisle, including Senator Jeffords, Dodd, Frist, and Kennedy, stated their strong interest in implementing new limits on law enforcement officials' current access to medical records, and Senator Collins specifically criticized the Administration for not moving independently to address this issue. The Committee requested that the Department of Justice report back to them with a list of concessions that they would be willing to make on this issue. DOJ recently drafted a response that defends the agency's current policy but does not take significant steps towards addressing the concerns expressed by the Labor Committee. For example, DOJ is now prepared to agree that the agency should be required to destroy or return medical records after they have finished using them for law enforcement purposes. However, they still have not indicated that they would be willing to accept even the most fundamental provisions included in all three of the Senate bills, which would require law enforcement officials to use some type of legal instrument, such as a warrant, a subpoena, or a court order, before accessing identifiable health information.

We are currently holding the DOJ response and are recommending to you that we wait until after the Labor Committee mark-up on May 25 in order to ensure that our response is not substantively at odds with the current bipartisan Congressional position on this issue. If this approach is acceptable to you, we will proceed accordingly.

After the mark-up, we will want to discuss with you whether it is appropriate to alter our position on the law enforcement issue and, if so, how best to proceed.

Medical Privacy Issues

- *Law enforcement access.* In the Shalala report, the Administration supported no change to law enforcement's current access to medical records. All of the major Senate bills are more protective of patient privacy, requiring subpoenas or warrants before police and other officials can see patient records.

- *Preemption of state laws.* The Administration is currently allied with privacy advocates in setting a federal floor of privacy protection but allowing states to set stricter standards. The business community and Republicans may kill the bill rather than accept that position. A compromise may exist, at the proper time, to set the bar high and then accept preemption except for carve-outs such as mental health, where stricter state laws would still be allowed.

- *Sharing of research information.* All of the bills agree that patient records can be shared for core medical research approved by investigatory review boards. A complex debate has arisen about how far "research" should be extended, and especially how best to protect privacy in privately funded research. The Administration may need flexibility on how to reach agreement on this issue.

- *Disclosure for "treatment and payment."* Our proposal would not require patient consent where disclosures be made for "treatment and payment." Privacy advocates have pushed for consent in all instances, while industry is pushing to consider many marketing actions as "treatment and payment." There are some tough line-drawing problems here, and again we may need flexibility.

6:30 Friday
W/ Katzen, Swire, Beier Jennings edits.

U.S. Department of Justice

Office of the Deputy Attorney General

Special Counsel for Health Care Fraud *Washington, D.C. 20530*

The Honorable James M. Jeffords
Chairman
Committee on Health, Education, Labor and Pensions
United States Senate
Washington, D.C. 20510-6300

Dear Mr. Chairman:

Thank you for the opportunity to present the views of the Department of Justice on behalf of the law enforcement community on pending legislation to protect the confidentiality of personal medical information. We look forward to working with the Committee to protect the privacy of confidential health information, while preserving the ability of Federal, state and local law enforcement agencies to enforce the laws within their jurisdictions and to oversee the integrity of the health care payment system.

The Department recognizes that additional safeguards may be necessary to prevent future abuses of medical records privacy, particularly in response to the growing use of computers to store, analyze, and distribute confidential health information. Morever, the Department believes it would be appropriate to establish reasonable restrictions on law enforcement access to, and use of, confidential health information that reflect current law and practice. The Department offers the following specific suggestions on how to strike the appropriate balance between the need to protect confidential health information and the need to protect public health and safety and investigate and punish illegal activity.

At a minimum, medical records privacy legislation should prohibit Federal, state and local law enforcement agencies and employees from obtaining or using such information except for official law enforcement activities. In addition, as a general principle, we believe it would be appropriate to codify current practice by requiring law enforcement to use lawful compulsory process, such as a search warrant, grand jury subpoena, summons, warrant, judicial subpoena, administrative subpoena or a civil investigative demand in order to obtain protected health

information; provided, that the legislation include limited but important exceptions, discussed below, that are necessary to protect public health and safety.

The Department supports legislation that requires law enforcement agencies to take appropriate and reasonable steps to minimize the public disclosure of identifiable health information, consistent with the requirements of due process and the needs of law enforcement to present a complete case. Law enforcement should also be required to destroy or return medical records to the original record-holder when the official law enforcement activity requiring the retention of those records has concluded, and no other applicable law or regulation requires that the medical records be retained.

We support reasonable restrictions on law enforcement access to and use of confidential health information. We also believe medical records privacy legislation should not unduly hinder the ability of Federal, state and local law enforcement to investigate and prosecute illegal activity and to protect the integrity of the health care payment system. Thus, we believe the requirement for law enforcement to use compulsory process, discussed above, should not apply in four circumstances: (1) when law enforcement is performing a health oversight function authorized by law (subject to the derivative use limitations discussed below); (2) pursuant to Federal, state or local mandatory reporting laws (including laws requiring the reporting of gunshot wounds, rapes, abuse of children or the elderly, or diversion of controlled substances); (3) in time-sensitive circumstances to prevent threatened or imminent physical harm to any person; and (4) when necessary to obtain limited name or other essential identifying information to enable law enforcement to locate and identify a patient who is a fugitive, suspect, or material witness.

With respect to the issue of derivative use, there are special concerns that may arise when law enforcement obtains access to large numbers of health records during health oversight activities. Therefore, we recommend that law enforcement should not be permitted to use information discovered during the oversight function against a patient for an unrelated, non-health care matter, unless authorized by a court under procedures similar to those in 18 U.S.C. 3486(e). However, because these concerns are not replicated when law enforcement obtains health records in non-health oversight law enforcement activities pursuant to compulsory process, any legislation should reflect current law which provides no restriction on the derivative use of confidential health information obtained by a law enforcement agency in the discharge of its general (i.e., non-health oversight) enforcement responsibilities.

Finally, we believe jails, prisons and detention facilities present unique situations with respect to medical records privacy. While the Department supports legislation that restricts correctional facilities and employees from disclosing, using or obtaining medical information, we believe such institutions should be exempted from the general obligations and duties imposed by medical record privacy legislation. These facilities also should be permitted to exchange prisoner or detainee health records without patient authorization with community health care providers providing health care services to the prisoners or detainees.

There are other technical drafting issues on which we would like to work with the Committee, including issues relating to certain definitions, the procedures for the imposition of penalties for violations, and government legal department access to health records from governmental departments and agencies while representing these bodies in civil matters prior to the initiation of legal proceedings.

Sincerely,

John T. Bentivoglio

cc: The Honorable Edward M. Kennedy
Ranking Minority Member

to Gary —
this version make
any difference

DRAFT

U.S. Department of Justice

Office of the Deputy Attorney General

Edits from Fri am

Special Counsel for Health Care Fraud *Washington, D.C. 20530*

Katzen, Beier, Swire comments (more to come from Jennings)

The Honorable James M. Jeffords
Chairman
Committee on Health, Education, Labor and Pensions
United States Senate
Washington, D.C. 20510-6300

Dear Mr. Chairman:

Thank you for the opportunity to present the views of the Department of Justice on behalf of the law enforcement community on pending legislation to protect the confidentiality of personal medical information. ~~As I testified on April 27,~~ we look forward to working with the Committee to protect the privacy of confidential health information, while preserving the ability of Federal, state and local law enforcement agencies to enforce the laws within their jurisdictions and to oversee the integrity of the health care payment system. ~~We believe the Department can and should play a constructive role in this effort, and Departmental representatives already have met with Committee staff to provide technical drafting assistance~~.

~~Existing laws at the federal, state and local level and internal policies and procedures have been sufficient to protect against widespread abuse of medical records privacy by law enforcement agencies. Nonetheless~~, The Department recognizes that additional safeguards may be necessary to prevent future abuses, particularly in response to the growing use of computers to store, analyze, and distribute confidential health information. Morever, the Department believes that reasonable restrictions on law enforcement access to, and use of, confidential health information that ~~essentially codify~~ current law and practice would not unduly burden law enforcement agencies or jeopardize public safety. ~~With these general principles in mind~~, The Department offers the following specific suggestions on how to strike the appropriate balance between the need to protect confidential health information and the need to protect the health and safety of the public and investigate and punish illegal activity.

of medical records privacy

reflect

Katzen, Beier, Swire comments

DRAFT

At a minimum, medical records privacy legislation should prohibit Federal, state and local law enforcement agencies and employees from obtaining or using such information except for official law enforcement activities. In addition, as a general principle, we believe it would ~~not~~ be ~~unduly burdensome~~ appropriate to codify current practice by requiring law enforcement to use lawful compulsory process, such as a search warrant, grand jury subpoena, summons, warrant, judicial subpoena, administrative subpoena or a civil investigative demand in order to obtain protected health information; provided, that the legislation include limited but important exceptions, discussed below, that reflect current law and practice and are necessary to protect public health and safety.

Lesko K. 6-28-99

The Department ~~also would~~ support legislation that requires law enforcement agencies to take appropriate and reasonable steps to minimize the public disclosure of identifiable health information, consistent with the requirements of due process. ~~and the needs of law enforcement to present a complete case~~ STET. Law enforcement should also be required to destroy or return medical records to the original record-holder when the official law enforcement activity requiring the retention of those records has concluded, and no other applicable law or regulation requires that the medical records be retained.

~~While~~ We support reasonable restrictions on law enforcement access to and use of confidential health information, ~~we~~ we also believe medical records privacy legislation should not unduly hinder the ability of Federal, state and local law enforcement to investigate and prosecute illegal activity and to protect the integrity of the health care payment system. Thus, we believe the requirement for law enforcement to use compulsory process, discussed above, should not apply in four circumstances: (1) when law enforcement is performing health oversight functions; (2) pursuant to Federal, state or local mandatory reporting laws (including laws requiring the reporting of gunshot wounds, rapes, abuse of children or the elderly, or diversion of controlled substances); (3) in time-sensitive circumstances to prevent threatened or imminent physical harm to any person; and (4) ~~when necessary~~ to obtain limited ~~information necessary to~~ locate and identify a patient who is a fugitive, suspect, or material witness. ~~In these limited circumstances, Federal law should not unduly hinder the ability of Federal, state and local law enforcement agencies to respond promptly to illegal activities and to protect public health and safety.~~

With respect to the issue of derivative use, in order to accommodate special concerns which may arise when law enforcement obtains access to large numbers of health records during health

subject to the derivative use limitations discussed below

name or other essential identifying ~~information~~

information to enable law enforcement to

Katzen, Beier, Swire comments

DRAFT

pursuant to compulsory process

oversight activities, we believe law enforcement should not be permitted to use information discovered during the oversight function against a patient for an unrelated, non-health care matter, unless a procedure analogous to that created by the Health Insurance Portability and Accountability Act of 1996 (codified at 18 U.S.C. § 3486(e)) is followed. However, because these concerns are not replicated when law enforcement obtains health records in non-health oversight law enforcement activities, we believe there should be no restriction on derivative use of confidential health information obtained by a law enforcement agency in the discharge of its general (i.e., non-health oversight) enforcement responsibilities.

STET

Finally, we believe jails, prisons and detention facilities present unique situations with respect to medical records privacy. While the Department supports legislation that restricts correctional facilities and employees from disclosing, using or obtaining medical information, we believe such institutions should be exempted from the general obligations and duties imposed by medical record privacy legislation. These facilities also should be permitted to exchange prisoner or detainee health records without patient authorization with community health care providers providing health care services to the prisoners or detainees.

are

There other technical drafting issues on which would like to work with the Committee, including issues relating to certain definitions, the procedures for the imposition of penalties for violations, and government legal department access to health records from governmental departments and agencies while representing these bodies in civil matters prior to the initiation of legal proceedings.

Sincerely,

John T. Bentivoglio

cc: The Honorable Edward M. Kennedy
Ranking Minority Member

Total Pages: 6

LRM ID: RJP70

EXECUTIVE OFFICE OF THE PRESIDENT
OFFICE OF MANAGEMENT AND BUDGET
Washington, D.C. 20503-0001

URGENT

Thursday, May 6, 1999

LEGISLATIVE REFERRAL MEMORANDUM

TO: Legislative Liaison Officer - See Distribution below

FROM: Janet R. Forsgren (for) Assistant Director for Legislative Reference
OMB CONTACT: Robert J. Pellicci
PHONE: (202)395-4871 FAX: (202)395-6148
SUBJECT: **JUSTICE Report on S578 Health Care Personal Information Nondisclosure Act of 1999 (Health Care PIN Act)**

DEADLINE: **NOON Tuesday, May 11, 1999**

In accordance with OMB Circular A-19, OMB requests the views of your agency on the above subject before advising on its relationship to the program of the President. **Please advise us if this item will affect direct spending or receipts for purposes of the "Pay-As-You-Go" provisions of Title XIII of the Omnibus Budget Reconciliation Act of 1990.**

COMMENTS: Senate Health, Education, Labor and Pensions Committee markup of medical records privacy legislation is scheduled for Tuesday, May 25th.

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- Sandra Yamin

LRM ID: RJP70 **SUBJECT:** JUSTICE Report on S578 Health Care Personal Information Nondisclosure Act of 1999 (Health Care PIN Act)

RESPONSE TO
LEGISLATIVE REFERRAL
MEMORANDUM

If your response to this request for views is short (e.g., concur/no comment), we prefer that you respond by e-mail or by faxing us this response sheet. If the response is short and you prefer to call, please call the branch-wide line shown below (NOT the analyst's line) to leave a message with a legislative assistant.

You may also respond by:
(1) calling the analyst/attorney's direct line (you will be connected to voice mail if the analyst does not answer); or
(2) sending us a memo or letter
Please include the LRM number shown above, and the subject shown below.

TO: **Robert J. Pellicci Phone: 395-4871 Fax: 395-6148**
Office of Management and Budget
Branch-Wide Line (to reach legislative assistant): 395-7362

FROM: _____ **(Date)**

_____ **(Name)**

_____ **(Agency)**

_____ **(Telephone)**

The following is the response of our agency to your request for views on the above-captioned subject:

_____ **Concur**

_____ **No Objection**

_____ **No Comment**

_____ **See proposed edits on pages** _____

_____ **Other:** _____

_____ **FAX RETURN of** _____ **pages, attached to this response sheet**

[redacted]

U.S. Department of Justice
Office of Legislative Affairs

Office of the Assistant Attorney General Washington, D.C. 20530

Pellichi

The Honorable James M. Jeffords
Chairman
Committee on Health, Education, Labor and Pensions
United States Senate
Washington, D.C. 20510-6300

Dear Mr. Chairman:

Thank you for the opportunity to present the views of the Department of Justice on behalf of the law enforcement community on pending legislation to protect the confidentiality of personal medical information. As Mr. John Bentivoglio, Special Counsel for Health Care Fraud, testified before the Committee on April 27, we look forward to working with the you to support this important goal, while preserving the ability of the Department of Justice to enforce the laws within its jurisdiction, and also to oversee the integrity of the health care payment system. We believe that the Department can and should play a constructive role in this effort.

Subsequent to the hearing, we have reviewed the three primary medical record proposals pending in the Senate, S. 578, S. 573 and S. 881, with an eye toward addressing the concerns voiced by members during our testimony. In addition, the Department has met several times with the Staff of the Committee, to further explore these issues. We believe that the Department can support a number of important principles governing law enforcement access to and use of personal medical records, which would advance the protection of medical record privacy in a manner that would at the same time preserve the ability of law enforcement to obtain important evidence when necessary:

- Law enforcement agencies and employees should be permitted to obtain and use medical records ~~only~~ for official law enforcement activities.

- Law enforcement agencies and employees when pursuing an official oversight investigation, or related criminal or civil proceeding, should be permitted to obtain individually identifiable medical records for that purpose.

- When law enforcement obtains medical records in the course of administrative, civil or criminal health care fraud oversight activities, law enforcement should be restricted from using those records against an individual patient whose record is obtained, except: 1) where the medical record is relevant to an investigation of the patient relating to billing for health care; or 2) where the law enforcement agency makes an application for, and obtains, a judicial disclosure order in an ex-parte proceeding analogous to the provisions of 18 U.S.C. § 3486(e).

- As a general matter, law enforcement should continue to be permitted to obtain medical records of a patient pursuant to lawful compulsory process, including a grand jury subpoena, a warrant, a judicial subpoena, an administrative subpoena, an authorized investigative demand, or a civil investigative demand.

- In exigent circumstances, in order to prevent threatened or imminent harm to a patient or another person, law enforcement should be permitted to obtain the medical records of that patient, without compulsory process. In other exigent circumstances, not involving threatened or imminent harm, law enforcement should be permitted to obtain without compulsory process, limited information contained in medical records, to locate and identify a patient who is a fugitive, a suspect, or a material witness.

- Medical record privacy legislation should not preempt federal or state mandatory reporting laws which require the disclosure of limited medical information to law enforcement agencies, including the Drug Enforcement Agency. Such laws include, but are not limited to, mandatory reporting of gunshot wounds, abuse and neglect of children, elders, spouses; rape; and diversion of scheduled pharmaceuticals.

What steps will DOJ take to protect the information it uses? Such as —

- Whistleblowers should be permitted to disclose medical records to law enforcement either directly or in the course of False Claims Act proceedings, when the disclosure of the medical records is related to the reporting potential false claims or fraud, or relevant to an official law enforcement activity;

- Law enforcement should be required when it is necessary to disclose medical information in public forums, such as court filings or trials, either to redact the medical records to the extent practicable, or to take other appropriate and reasonable steps to minimize the public disclosure of identifiable health information, consistent with the requirements of due process and the direction of the appropriate judicial or administrative hearing officer.

- The provisions governing the procedures for imposing and appealing civil penalties should make clear that they envision an administrative proceeding to review civil monetary penalties imposed by the Secretary of Health and Human Services, and do not contemplate a civil court proceeding by the Secretary in the United States District Courts. If a new cause of action in federal District Court for a civil fine is created, the Attorney General should be responsible for enforcing such a provision. How does this relate to qui tams?

- Any provision that provides for injunctive relief to prevent or terminate violations of the statute, should be enforceable by the Attorney General.

- Law enforcement should be required to destroy or return medical records to the original record-holder when the official law enforcement activity requiring the retention of those records has concluded, and no other applicable law or regulation requires that the medical records be retained by law enforcement.

- References to law enforcement should include federal, state and local law enforcement.

- Special concerns govern the operation of jails, prisons and detention facilities. These institutions perform hybrid functions that run from law enforcement to actually providing medical care to prisoners and

detainees. These special concerns should be addressed by generally exempting these institutions from the obligations and duties imposed by medical record privacy legislation. However, these institutions should be restricted from disclosing, using or obtaining medical information, except for an official activity. Also, the final language legislative language governing these facilities, must insure that they are permitted to exchange prisoner or detainee health records, without patient authorization, with community health care providers who provide health care services to the prisoners or detainees.

We believe that medical record privacy legislation that incorporates these principles would substantially enhance the protection of medical record privacy, while preserving the ability of law enforcement to perform its important duties. Many of these principles are already incorporated in one or more of the bills. The Department looks forward to continuing to work with you, the Committee and the staff on this important legislation.

Thank you for the opportunity to present our views on this matter. If we may be of additional assistance, we trust that you will not hesitate to call upon us. The Office of Management and Budget has advised that there is no objection from the standpoint of the Administration's program to the presentation of this report.

Sincerely,

Jon P. Jennings,
Acting Assistant Attorney General

cc. The Honorable Edward M. Kennedy,
Ranking Minority Member

Total Pages: 6

LRM ID: RJP70

EXECUTIVE OFFICE OF THE PRESIDENT
OFFICE OF MANAGEMENT AND BUDGET
Washington, D.C. 20503-0001

URGENT

Thursday, May 6, 1999

LEGISLATIVE REFERRAL MEMORANDUM

TO: Legislative Liaison Officer - See Distribution below

FROM: Janet R. Forsgren (for) Assistant Director for Legislative Reference
OMB CONTACT: Robert J. Pellicci
PHONE: (202)395-4871 FAX: (202)395-6148
SUBJECT: **JUSTICE Report on S578 Health Care Personal Information Nondisclosure Act of 1999 (Health Care PIN Act)**

DEADLINE: **NOON Tuesday, May 11, 1999**

In accordance with OMB Circular A-19, OMB requests the views of your agency on the above subject before advising on its relationship to the program of the President. **Please advise us if this item will affect direct spending or receipts for purposes of the "Pay-As-You-Go" provisions of Title XIII of the Omnibus Budget Reconciliation Act of 1990.**

COMMENTS: Senate Health, Education, Labor and Pensions Committee markup of medical records privacy legislation is scheduled for Tuesday, May 25th.

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_____ **(Name)**

_____ **(Agency)**

_____ **(Telephone)**

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_____ **Concur**

_____ **No Objection**

_____ **No Comment**

_____ **See proposed edits on pages** _____

_____ **Other:** _____

_____ **FAX RETURN of** _____ **pages, attached to this response sheet**

U.S. Department of Justice
Office of Legislative Affairs

Office of the Assistant Attorney General Washington, D.C. 20530

The Honorable James M. Jeffords
Chairman
Committee on Health, Education, Labor and Pensions
United States Senate
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Thank you for the opportunity to present our views on this matter. If we may be of additional assistance, we trust that you will not hesitate to call upon us. The Office of Management and Budget has advised that there is no objection from the standpoint of the Administration's program to the presentation of this report.

Sincerely,

Jon P. Jennings,
Acting Assistant Attorney General

cc. The Honorable Edward M. Kennedy,
Ranking Minority Member

OFFICE OF MANAGEMENT AND BUDGET

Legislative Reference Division

Labor-Welfare-Personnel Branch

Telecopier Transmittal Sheet

URGENT

FROM: Bob Pellicci -- 395-4871

DATE: 5/20 **TIME:** 4 35 P.M.

Pages sent (including transmittal sheet): 10

COMMENTS: OASIS revisions per Dan, Peter Swire & Health Division - Need your okay/comments no later than 10 am tomorrow, May 21st. Thanks.

TO: Chris / Devorah

PLEASE CALL THE PERSON(S) NAMED ABOVE FOR IMMEDIATE PICK-UP.

REVISED 05/21/99

DRAFT TESTIMONY
JEFF KANG, M.D., DIRECTOR
OFFICE OF CLINICAL STANDARDS AND QUALITY
HEALTH CARE FINANCING ADMINISTRATION
on the
HOME HEALTH CARE
OUTCOME & ASSESSMENT INFORMATION SET (OASIS)
before the
SENATE SELECT COMMITTEE ON AGING
MAY 24, 1999

Chairman Grassley, Senator Breaux, distinguished committee members, thank you for inviting us to discuss our efforts to improve home health care quality through better patient assessment and measurement of the outcomes of care. We are required by law to survey the quality of home health care with a "standardized, reproducible" assessment instrument. To improve care and comply with the law, we will be using the Outcome and Assessment Information Set (OASIS).

OASIS helps home health agencies determine what patients need, develop the right plan for their care, assess that care over the course of treatment, and learn how to improve the quality of that care. It incorporates all the information about patients' health and functional status, health service use, living conditions, and social support that are needed to support all the home health agencies' responsibilities. **In addition to monitoring quality,** OASIS also is essential for accurate payment under the new home health prospective payment system that the law requires us to use beginning October 1, 2000. We will be requiring use of OASIS by home health agencies as a Condition of Participation in the Medicare and Medicaid programs this year.

The important benefits of OASIS must be implemented in a way that protects personal privacy. At HCFA, we have an excellent historical record of safeguarding sensitive beneficiary information. Our agency provides greater protection for personal medical information than generally exists in the private sector, and we are actively participating in the

Administration's inter-agency process to make Secretary Shalala's recommendations for medical privacy work on the operational level.

In recent months, we have come to realize that stronger privacy protections must be built into the structure of our new operations. President Clinton and Vice President Gore have both spoken about the paramount importance they attach to medical records privacy. This is why the Administration has been a consistent advocate for effective medical records privacy legislation. I am pleased to announce some new steps we are taking to assure the privacy of patients while maintaining the legitimate focus of the OASIS program, such as:

- **Careful drafting of a notice that Medicare and Medicaid patients will receive. The notice will explain why OASIS data is collected, and inform patients of their right to see and request corrections of the data.**

- **Limitations on "routine uses" of data under the Privacy Act, so that personally identifiable data will only be used where statistical information is not sufficient. Among other changes, personally identifiable data will no longer go to accrediting organizations such as the Joint Commission for Accreditation of Health Organizations.**

- **Major changes in the treatment of private-pay patients under OASIS. We have decided that information on non-Medicare and non-Medicaid patients will *not* be transmitted to the states or the agency in personally identifiable form.**

- **Acceleration of efforts to encrypt data during transmission, to provide yet another level of protection. Note: David Beier asked whether anything can be said about deadlines or goals for implementation of this.**

~~We have taken several steps to address privacy concerns raised by Vice President Gore and others. No Administration has been more committed to protecting medical privacy. Our agency has a solid track record of consistently safeguarding sensitive beneficiary information. In fact, we provide much greater protection for such information than is afforded in the private sector. For OASIS data, we are providing even more security beyond our usual, stringent protections.~~

- ~~We will explicitly notify Medicare and Medicaid patients of:~~
  - ~~why OASIS data is collected;~~
  - ~~their right to see, copy, and request corrections of the data;~~
  - ~~their right to confidentiality and the specific Privacy Act rules which apply; and~~
  - ~~their right to not answer OASIS questions.~~
- ~~We will have home health agencies remove OASIS data on patient financial factors before reporting it to Medicare and Medicaid.~~
- ~~We will have home health agencies remove all information that could potentially identify individuals who are not enrolled in Medicare or Medicaid.~~
- ~~And we are accelerating efforts to encrypt data to provide yet another layer of protection.~~

We are also making special efforts to help home health agencies learn how to use this valuable tool. Research conducted by the University of Colorado shows that it takes home health care professionals about eight patient assessments to become proficient in using OASIS.

Once past that learning curve, OASIS actually slightly reduces the total time it takes to conduct a thorough patient assessment. Home health care professionals who have used OASIS in demonstration projects agree that it takes no longer to use than their previous assessment methods. However, because OASIS is structured in a checklist format, home health staff using it spend less of the total evaluation time writing out a narrative of their assessment findings and more time with the patient.

Efforts to help providers through the OASIS learning curve include:

- a satellite broadcast training session on August 20, 1998 to XX sites across the country reaching ?30,000? home health care professionals (tapes of this session are also available);
- numerous presentations at industry trade association meetings;
- distribution of a free, detailed manual on how to collect OASIS data, use the software, and report the data;
- manuals, software, updates, and other additional assistance that can be downloaded from the Internet at *hcfa.gov*, and *hcfa.gov/medicare/hsqb/oasis/oasishmp.htm*;
- answers to questions on installing OASIS software via a toll-free telephone line at 1-877-201-4721 and via E-mail *haven help@ifmc.org*;
- establishing OASIS Educational Coordinators in all States;
- a week long conference last September to teach State personnel about OASIS; and
- a "train the trainer" program last October for all State OASIS Educational Coordinators to provide materials and detailed information on how to teach home health care professionals in their State how to use OASIS.

Background

Home health patients are among the most vulnerable Medicare and Medicaid beneficiaries. They tend to have more health problems, and the fact that care is delivered in the home makes monitoring the quality of that care more challenging. The Omnibus Budget Reconciliation Act of 1987 mandated that Medicare survey the quality of home health care and services with a "standardized, reproducible" assessment instrument. The following year we contracted with University of Colorado researchers and clinicians to develop such an instrument. We have been working ever since to refine and validate what has become OASIS.

OASIS provides a standardized format for the patient assessments that home health agencies have been doing all along. It does not require additional effort for agencies that have been conducting the

thorough patient assessments that are needed in order to provide appropriate care. OASIS incorporates only information needed to support concrete indicators of patient need and quality of care. ~~For example, it records whether a patient is depressed in order to track progress in treating that depression.~~ **[delete or choose a less controversial example]**

The 79 data elements in OASIS were developed by clinicians and are valid, reliable, and risk adjusted, taking into account all characteristics of patient populations. This ensures that assessments done by different health care professionals with OASIS consistently yield the same results. It also ensures that quality measurement takes into account whether agencies are caring for ~~low-income or~~ sicker patients and therefore might have what otherwise would appear to be poorer care or outcomes.

OASIS has been used by 162 home health agencies in various demonstration projects around the country. It has been tested in a national Outcome-Based Quality Improvement demonstration involving 50 home health agencies of all sizes, and in a single-State demonstration project involving 22 agencies. A slightly abbreviated form of the OASIS has been used for quality improvement purposes in the national Medicare prospective payment demonstration, which includes 90 agencies in five States. **[Include brief argument as to why abbreviated data set was inadequate]**

OASIS is supported by the American Academy of Home Care Physicians, the National Alliance for the Mentally Ill, and many home health care providers who are voluntarily using OASIS because of its unprecedented value in promoting high quality care and comprehensive, accurate, clinical record-keeping. Home health care professionals using OASIS report that it is helping them to be more focused on the needs of individual patients, and to provide better care in fewer visits and with fewer subsequent hospitalizations.

Implementation

We first published a proposed rule for requiring use of OASIS by all home health agencies participating in the Medicare and Medicaid program in the *Federal Register* on March 10, 1997. Many comments on the proposed regulation suggested adding additional questions. However, to keep OASIS at a reasonable length, we instead will allow agencies flexibility to **expand** ~~tailor~~ OASIS ~~to~~ **for** their own patient population. For example, an agency that provides a larger share of mental health services can add extra questions related to mental health if it so chooses; **however, these data will not be transmitted.**

On January 25, 1999, we published a final regulation requiring use of OASIS and an interim final rule requiring that home health agencies encode and transmit the data to us. We had planned for home health agencies to begin mandatory reporting of OASIS data on April 26, 1999. However, on April 7 we announced that we would postpone the requirement in order to conduct a thorough evaluation of privacy concerns **and to complete the review of OASIS pursuant to the Paperwork Reduction Act of 1995.** ~~With those~~ **Once these** concerns ~~now~~ **are** addressed, we expect to publish a new date for the start of mandatory collection and ~~reporting~~ **will report it** in the *Federal Register*. ~~soon.~~

Once reporting begins, home health agencies will transmit computerized, coded OASIS data to State survey agencies using a private network with a direct phone connection. The State will compile the data and send it to the Health Care Financing Administration. OASIS system users must enter an ID and password at three different checkpoints before access is permitted. And, ~~at every step in the process,~~ the data **transmitted to the States and to HCFA** is fully protected under the federal Privacy Act. The Privacy Act has been effective in ensuring confidentiality of Medicare data.

We will develop a performance report for each home health agency based on its OASIS reports, including a comparison of its performance to the State and national average. That will allow home health agencies to identify their own weaknesses and improve the quality of care they provide. It also will allow us to compare the quality of care among agencies and thereby increase scrutiny for those that

need more oversight and assistance in improving quality. Eventually, we will share results with the public so consumers can make informed choices among home health agencies based on the quality of care they provide.

Data that can identify individual Medicare and Medicaid patients are critical to ensuring that we pay accurately for care and that we can monitor the quality of care. It allows evaluators to assess whether a home health patient's later admission to a hospital or nursing home might be related to gaps or problems with the care provided by the home health agency and identify potential areas for improvement. It is also essential **for ensuring accurate payment under the prospective payment system. In particular it links the OASIS data to actual claims data in order to create the proper weightings for reimbursement.**

As I stated earlier, all information that could be used to identify private pay patients will be removed by the home health agencies before OASIS data is reported **to HCFA and the State.**~~, and we will not require agencies to report data on private pay patients until systems for removing identifiable information are in place~~.

~~Data on private patients is collected in order to ensure consistent quality of care for all patients. It allows us to compare care provided to private pay and Medicare patients and make sure that incentives under the prospective payment system to provide care efficiently are not limiting appropriate care for Medicare patients. Collecting data on all patients, regardless of payer, is standard for all Medicare and Medicaid Conditions of Participation for home health agencies, as well as for Conditions of Participation for hospitals and other providers, and for quality assessments by private health care accreditation bodies, such as the Joint Commission on Accreditation of Health Care Organizations~~.

OASIS and Prospective Payment

OASIS data are critical to development, implementation, and accurate payment under the home health prospective payment system that Congress has required we implement in October 2000. We need to collect OASIS data as soon as possible in order to develop prospective payment rates and estimate their impact based on comprehensive national data. Doing so based on the limited OASIS research data available to us now could jeopardize our ability to pay accurately and to understand in advance how different types of agencies across the country will be affected.

The comprehensive information in OASIS is **necessary to** accurately determine the appropriate amount of care, and therefore the appropriate amount of payment for that care. **This is particularly important in the home health environment, which is complicated by confounding factors such as patient behavior.** Patient diagnosis alone, which is the basis for inpatient hospital prospective payment, predicts less than 10 percent of home health patients' need for service.

Using OASIS to both determine accurate payment and assess quality helps to minimize the burden on home health agencies. It also helps fight fraud and abuse, which has been a substantial problem in home health care, because it balances incentives. While prospective payment creates an incentive to "upcode" and say patients are sicker in order to receive higher payment, doing so with OASIS would result in poor quality indicators. That could trigger an investigation, as well as result in a competitive disadvantage when OASIS data are eventually shared with the public.

Using OASIS to monitor quality is even more essential under a prospective payment system. As mentioned above, prospective payment creates highly effective incentives to provide care efficiently, but those incentives must not be allowed to reduce appropriate care. OASIS will help providers accurately assess what the proper level of care is, and it will help us monitor that care to ensure that patients are getting all the care they need.

CONCLUSION

OASIS represents a significant advance in home health care. It is proven in rigorous testing to help improve the quality of patient care and the outcomes of that care. It allows home health care professionals to spend more time with patients and less time writing up assessments. It will help ensure accurate payment under the new prospective payment system. It will help ensure that beneficiaries receive high quality care. And it will help protect taxpayer dollars and the integrity of the Medicare and Medicaid programs. We are taking extra precautions, beyond our already stringent privacy protections for Medicare and Medicaid data, to ensure the confidentiality of OASIS information**, and we are communicating these precautions to all (Medicare, Medicaid, and private pay) patients before they receive home health care. In addition,** ~~And~~ we **are** working to help home health care professionals learn how to use this important new clinical advance. I thank you for holding this hearing, and I am happy to answer your questions.

# # #

American Medical Association
Physicians dedicated to the health of America

E. Ratcliffe Anderson, Jr., MD 515 North State Street 312 464-5000
Executive Vice President, CEO Chicago, Illinois 60610 312 464-4184 Fax

cc: Stein
Jenning

The Honorable John Podesta
White House Chief of Staff
White House
1600 Pennsylvania Avenue
1st Floor, West Wing
Washington, DC 20500

Dear Mr. Podesta:

On behalf or the American Medical Association, I would like to inform you about the strong support of our Association for passage of H.R. 354, legislation to prevent database piracy. As an organization that both develops and maintains sophisticated databases regarding health care, we are strongly supportive of legislation that protects these important resources. Action is needed to address domestic concerns as well as issues raised by the European Union's directive regarding database protections.

We understand that there are concerns by users of information as articulated in the Administration's testimony before the Judiciary Committee on March 18. We would like to reiterate, however, that passage of legislative that addresses these concerns is essential to our ability to continue to develop and maintain our databases.

Respectfully,

E. Ratcliffe Anderson Jr., MD

fax: 202-456-2883

U.S. Department of Justice

Office of the Deputy Attorney General

Washington, D.C. 20530

FAX TRANSMISSION SHEET

TO: Sally Katzen, 456-1605 Peter Swire, OMB, Fax 395-5167

Chris Jennings, 456-5767 David Beier, 456-7044

Phone: _____ **Fax:** _____

FROM: **John T. Bentivoglio**
Special Counsel for Health Care Fraud

Phone: (202) 514-2707 Fax: (202) 616-1239

DATE: 5/20/99

NUMBER OF PAGES (including this cover sheet): 4

MESSAGE: Revised medical record privacy letter

Note: The information in this facsimile should be considered confidential.

U.S. Department of Justice

Office of the Deputy Attorney General

Special Counsel for Health Care Fraud *Washington, D.C. 20530*

DRAFT

The Honorable James M. Jeffords
Chairman
Committee on Health, Education, Labor and Pensions
United States Senate
Washington, D.C. 20510-6300

Dear Mr. Chairman:

Thank you for the opportunity to present the views of the Department of Justice on behalf of the law enforcement community on pending legislation to protect the confidentiality of personal medical information. As I testified on April 27, we look forward to working with the Committee to protect the privacy of confidential health information, while preserving the ability of Federal, state and local law enforcement agencies to enforce the laws within their jurisdictions and to oversee the integrity of the health care payment system. We believe the Department can and should play a constructive role in this effort, and Departmental representatives already have met with Committee staff to provide technical drafting assistance.

Existing laws at the Federal, state and local level and internal policies and procedures have been sufficient to protect against widespread abuse of medical records privacy by law enforcement agencies. Nonetheless, the Department recognizes that additional safeguards may be necessary to prevent future abuses, particularly in response to the growing use of computers to store, analyze, and distribute confidential health information. Morever, the Department believes that reasonable restrictions on law enforcement access to, and use of, confidential health information that essentially codify current law and practice would not unduly burden law enforcement agencies or jeopardize public safety. With these general principles in mind, the Department offers the following specific suggestions on how to strike the appropriate balance between the need to protect confidential health information and the need to protect the health and safety of the public and investigate and punish illegal activity.

At a minimum, medical records privacy legislation should prohibit Federal, state and local law enforcement agencies and employees from obtaining or using such information except for official law enforcement activities. In addition, as a general principle, we believe it would not be unduly burdensome to codify current practice by requiring law enforcement to use lawful compulsory process, such as a search warrant, grand jury subpoena, summons, warrant, judicial subpoena, administrative subpoena or a civil investigative demand in order to obtain protected health information; provided, that the legislation include limited but important exceptions, discussed below, that reflect current law and practice and are necessary to protect public health and safety.

The Department also would support legislation that requires law enforcement agencies to take appropriate and reasonable steps to minimize the public disclosure of identifiable health information, consistent with the requirements of due process, and the needs of law enforcement to present a complete case. Law enforcement should also be required to destroy or return medical records to the original record-holder when the official law enforcement activity requiring the retention of those records has concluded, and no other applicable law or regulation requires that the medical records be retained.

While we support reasonable restrictions on law enforcement access to and use of confidential health information, we believe medical records privacy legislation should not unduly hinder the ability of Federal, state and local law enforcement to investigate and prosecute illegal activity and to protect the integrity of the health care payment system. Thus, we believe the requirement for law enforcement to use compulsory process, discussed above, should not apply in four circumstances: (1) when law enforcement is performing health oversight functions; (2) pursuant to Federal, state or local mandatory reporting laws (including laws requiring the reporting of gunshot wounds, rapes, abuse of children or the elderly, or diversion of controlled substances); (3) in time-sensitive circumstances to prevent threatened or imminent physical harm to any person; and (4) when necessary to obtain limited information necessary to locate and identify a patient who is a fugitive, suspect, or material witness. In these limited circumstances, Federal law should not unduly hinder the ability of Federal, state and local law enforcement agencies to respond promptly to illegal activities and to protect public health and safety.

With respect to the issue of derivative use, in order to accommodate special concerns which may arise when law enforcement obtains access to large numbers of health records during health

oversight activities, we believe law enforcement should not be permitted to use information discovered during the oversight function against a patient for an unrelated, non-health care matter, unless a procedure analogous to that created by the Health Insurance Portability and Accountability Act of 1996 (codified at 18 U.S.C. § 3486(e)) is followed. However, because these concerns are not replicated when law enforcement obtains health records in non-health oversight law enforcement activities, we believe there should be no restriction on derivative use of confidential health information obtained by a law enforcement agency in the discharge of its general (i.e., non-health oversight) enforcement responsibilities.

Finally, we believe jails, prisons and detention facilities present unique situations with respect to medical records privacy. While the Department supports legislation that restricts correctional facilities and employees from disclosing, using or obtaining medical information, we believe such institutions should be exempted from the general obligations and duties imposed by medical record privacy legislation. These facilities also should be permitted to exchange prisoner or detainee health records without patient authorization with community health care providers providing health care services to the prisoners or detainees.

There other technical drafting issues on which would like to work with the Committee, including issues relating to certain definitions, the procedures for the imposition of penalties for violations, and government legal department access to health records from governmental departments and agencies while representing these bodies in civil matters prior to the initiation of legal proceedings.

Sincerely,

John T. Bentivoglio

cc: The Honorable Edward M. Kennedy
Ranking Minority Member

DATE: 5-20-99

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REMARKS:

HELP draft 5/18/99

Top Issues

1. Notice of Information Practices. The requirements for the Notice of Confidentiality Information do not include key information eg. actual uses and recipients of the information, confidentiality practices employed by the holder of the information, how to obtain additional information. Also doesn't require that it be given to the individual.

2. Content and Structure of the Authorizations. The requirements for authorizations provide inadequate information and privacy protections, and also appear to be unworkable as a practical matter. There is no requirement that the authorization for treatment/payment state that plan enrollment is conditioned upon signing the authorization, or inform the person that he can opt-out and self-pay for an episode of care. Since this authorizations is coerced (the plan may refuse enrollment if the authorization is not signed), failure clearly to limit the authorizations to treatment/payment makes many of the protections in the rest of the bill meaningless

There is no requirement that the authorization for purposes other than treatment/payment state that the person need not sign the authorization in order to get treatment/payment. If this is not stated on the face of the authorization, the person could easily not understand that signing the authorization is voluntary.

3. Loophole in the Definition of "Health Care Operations." As drafted, this definition appears to include activities "implementing the terms of a contract for health plan benefits." This open ended clause is limited only by four broadly phrased provisions describing the universe of health care operations. This could make many of the protections in the rest of the bill meaningless. We are working with staff to fix this language. Additionally, the definition does not limit "Operations" uses / disclosures to those internal to the plan that obtains the information from the individual.

4. Definition of Nonidentifiable Health Information. Under this definition, if the obvious identifiers (name, SSN, birthdate) have been removed or encoded, the information is deemed nonidentifiable. This oversimplifies identifiability. This definition wrongly assumes that an individual cannot be identified even after these types of "identifiers" have been removed or coded. It assumes that a "key" would be required to reveal the subject's identity. However, coded data can still be easily identifiable data. This definition limits the bill's protections to too narrow a range of information.

The definition should focus on whether or not, or how hard it is, to identify the person -- not on what has been done to the information. It should incorporate a concept of reasonableness or directness or both, much like the definition in the S.578 as introduced. That is, information should be "identifiable" if it is reasonable to believe that predictable recipients of the information could, based on the information alone or in combination with other information to which the recipient is likely to have access, identify the subject. This (or an even more protective) approach is taken by most HHS agencies today.

5. Research. "Pure Research." The definition of protected health information (PHI) now also includes any banked cells or tissue–this means that any information derived from research using tissue/cells will be subject to all of the allowable disclosures in this bill. Research that is totally independent of the provision of health care (and which may have unproven relevance to the provision of health care) should not be subject to the same allowable disclosures as health care related information.

Coded Information. Because the definition of PHI excludes information if the obvious identifiers have been stripped or coded (see #4 above), a significant amount of information that today is protected by the Common Rule would no longer have such protection. Coded information should be subject to IRB or data review board approval of waiver of authorization for disclosure.

Membership and Operations Rules for the Data Review Boards. Under this draft, the data review boards reviewing private sector research establish their own rules for complying with the statute. They should be subject to implementing regulations established by the Secretary.

* What protections to private sector research apply in terms of IRB. (expedited review (1 ind.) vs. full board review

Other Major Issues

Private Right of Action. Under this draft, the plaintiff must prove an "intentional and willful" violation. The standard to prove a basic violation should be "knowing." The statute of limitations has also been shortened from 3 years to 2.

Research Purposes – Access to information obtain during a research study should be denied only where a board has approved the denial of access, and the patient has agreed to the denial of access when consenting to participate. A patient should be granted access to the information at the conclusion of the trial.

Accounting for Disclosures. The exception for disclosures to employees of the entity that maintains the record is over broad. If the employee works in a very different component of a large, even multi-national, corporation, the disclosure is more analogous to disclosures outside the record-keeper, and there should be an accounting.

Creation of Non-Identifiable Information. Under this draft, a holder of PHI may hire someone to transform PHI into nonidentifiable health information if they prohibit that person from using the PHI for any other purpose. This should not be left to contract, which the holder of PHI may have little incentive to enforce. The law should directly prohibit such agents from using the PHI for other purposes, so that violations are subject to the bill's enforcement provisions.

Deemed Disclosure of PHI. It is not clear from the existing language whether the manipulation of nonidentifiable information with intent to create PHI must be successful in order for there to be a violation. This should be clarified. We suggest revising this as follows: ". . . who manipulates a nonidentifiable database in an attempt (whether or not successful) to identify an individual . . . ."

Sally: go back today
W Lang but this is not Admin representation.

Emergency Circumstances -- Public health authorities should be explicitly mentioned as entities that are permitted to receive protected health information under emergency circumstances. In the event of a bioterrorist attack, which would constitute emergency circumstances, there will be legitimate reasons for permitting persons to disclose protected health information to health officials (e.g., to identify persons who should receive emergency treatment).

Section 207, Public Health. The language in Section 207 regarding disclosures to public health authorities (i.e., "for use in a legally authorized...") may be overly restrictive and not allow for various agents and collaborators (such as grantees) to receive the information. The language should give public health authorities broader discretion to designate appropriate recipients of the information consistent with current practice.

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or we'll get their Lang tomorrow.

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RTS OF MINORS.

AMENDMENT No. ____ intended to be proposed by _____.

ACLU language

Viz:

In section 204, strike subsection (d) and insert the following:

(d) RIGHTS OF MINORS.-- The rights of minors under this Act shall be exercised by a parent, the minor, or other person as provided for under the applicable State law, provided however that a minor who, acting alone or with legal authorization, may obtain a type of health care without violating any applicable law, shall exercise all the rights of the individual under this Act with respect to protected health information relating to such health care.

In section 401(a)(4), add "access to protected health information or health care services or" after "that relates to" on page 83, line 14.

(d) RIGHTS OF MINORS.—The rights of minors under this Act shall be exercised by a parent, the minor, or other person as provided for under applicable State law.

Needs to go back to old language

SEC. 205. EMERGENCY CIRCUMSTANCES.

(a) GENERAL RULE.—In the event of a threat of imminent physical or mental harm to the subject of protected health information, any person may, in order to allay or remedy such threat, disclose protected health information about such subject to a health care practitioner, health care facility, law enforcement authority, or emergency medical personnel. (add next sen.)

(b) HARM TO OTHERS.—Any person may disclose protected health information about the subject of the information where—

(1) such subject has made a direct or indirect threat of serious injury or death with respect to an individual or group of individuals;

(2) the subject has the ability to carry out such threat, or is engaged in carrying out the threat; and

(3) the release of such information is necessary to prevent or significantly reduce the possibility of such threat being carried out.

(c) GOOD FAITH BELIEF.—No disclosure made in the good faith belief that the disclosure was necessary to protect the health or safety of an individual or others from

TITLE IV—MISCELLANEOUS

SEC. 401. RELATIONSHIP TO OTHER LAWS.

(a) STATE AND FEDERAL LAW.—

(1) STATE LAW ENACTED PRIOR TO DATE OF ENACTMENT.—

(A) IN GENERAL.—Except as provided in this section, the provisions of this Act shall preempt State laws enacted prior to the date of enactment of this Act to the following extent:

(i) COPYING, INSPECTION, AND AMENDMENT.—The provisions of title I relating to the copying or inspection and amendment of protected health information shall preempt any such State law to the extent that such law relates to the right of an individual to inspect or copy protected health information pertaining to the individual, or the right of an individual with respect to the amendment of protected health information pertaining to the individual.

(ii) USE AND DISCLOSURE FOR TREATMENT, PAYMENT, AND HEALTH CARE OPERATIONS.—Sections 202 shall preempt any such State law to the extent

that such law relates to the use and disclosure of protected health information for purposes of treatment, payment or health care operations.

(iii) USE AND DISCLOSURE FOR RESEARCH.—Section 208 shall preempt any such State law to the extent that such law relates to the use and disclosure of protected health information for purposes of research.

(B) LIMITATION.—

(i) IN GENERAL.—Nothing in this Act shall be construed to preempt any provision of State law relating to the confidentiality of health information or health-related information if such provision of State law is not a law of the type described in subparagraph (A).

(ii) MORE PROTECTIVE STATE LAWS.—No provision of this Act described in subparagraph (A) shall be construed to preempt any State law enacted prior to the date of enactment of this Act if such State law is more protective of the confidentiality rights of individuals than such provision.

(2) STATE LAW ENACTED AFTER DATE OF ENACTMENT.—Except as provided in subsections (b) and (c), the provisions of this Act described in paragraph (1)(A) shall preempt any related provisions of a State law pertaining to the confidentiality of protected health information if such law is enacted after the date of enactment of this Act.

(3) CONSISTENCY WITH OTHER FEDERAL LAWS.—

(A) IN GENERAL.—Nothing in this Act shall be construed as altering, amending, modifying, invalidating, impairing or superseding, explicitly or implicitly, other Federal laws or regulations relating to protected health information or relating to an individual's access to protected health information or health care services.

(B) OTHER LAWS.—Nothing in this Act shall be construed to prevent an employer or its agent from complying with it's rights and responsibility under—

(i) the Americans with Disabilities Act of 1990 (29 U.S.C. 12101 et seq.) or any State or local law relating to discrimination on the basis of disability;

moved from previous section (employment (and use & disclosure) section)

(ii) the Family and Medical Leave Act of 1993 (29 U.S.C. 2601 et seq.) or any State or local law relating to family and medical leave; or

(iii) the Occupational Safety and Health Act of 1970 (29 U.S.C. 651 et seq.), the Federal Mine Safety and Health Act of 1977 (30 U.S.C. 801 et seq.), or any State or local law relating to workplace safety and health.

(4) MINORS.—Nothing in this Act shall be construed to preempt, modify, repeal or affect the interpretation of a provision of Federal or State law that permits or restricts access to h.c. services or relates to the disclosure of protected health information or any other information about a minor to a parent or guardian of such minor.

(b) PRIVILEGES.—Nothing in this section shall be construed to preempt or modify any provision of State statutory or common law to the extent that such law concerns a privilege of a witness or person in a court of that State. This title shall not be construed to supersede or modify any provision of Federal statutory or common law to the extent such law concerns a privilege of a witness or person in a court of the United States. Authorizations

pursuant to sections 202 shall not be construed as a waiver of any such privilege.

(c) CERTAIN DUTIES UNDER LAW.—Nothing in this section shall be construed to preempt, supersede, or modify the operation of any State law that relates to—

(1) the use and disclosure of information pertaining to mental health; or

(2) the use and disclosure of information pertaining to public health ~~consistent with~~ section 207;

to the extent that such State law prevents or otherwise restricts the use and disclosure of protected health information otherwise permissible under this Act.

(d) STATE FLEXIBILITY IN LAWS PROTECTING HEALTH INFORMATION RELATED TO WORKERS COMPENSATION AND LIABILITY INSURANCE.—

(1) FLEXIBILITY IN GENERAL.—

(A) NONAPPLICATION.—The requirements of this Act shall not apply to any person in connection with providing, administering, supporting, or coordinating benefits excepted under any of subparagraphs (B) through (F) and (H) of section 2791(c)(1) of the Public Health Service Act (42 U.S.C. 300gg-91(c)(1)(B)-(F) and (H)), so long as a State is found to be protec-

serious, imminent harm shall be a violation of, or punishable under, this Act.

(d) EXIGENT CIRCUMSTANCES.—

(1) IN GENERAL.—When exigent circumstances exist, any person may disclose protected health information upon the request of a law enforcement agency that is in hot pursuit of, ~~or is attempting to locate and identify~~, a fugitive, suspect, or material witness.

(2) GOOD FAITH BELIEF.—No disclosure made in the good faith belief that exigent circumstances exist, as described in paragraph (1), shall be a violation of, or punishable under, this Act.

SEC. 206. OVERSIGHT.

(a) IN GENERAL.—A health care provider, health plan, health researcher, employer, life insurer, law enforcement official, public health authority, school, or university shall disclose protected health information to a health oversight agency for purposes of, or in compliance with, an oversight function authorized by law.

(b) USE IN ACTION AGAINST INDIVIDUALS.—

(1) IN GENERAL.—Protected health information about an individual that is disclosed under this section may not be used in, or disclosed to any person

(C) specify that such information may not otherwise be disclosed or used; and

(D) meet any other requirements that the court determines are needed to protect the confidentiality of the information.

(c) APPLICABILITY.—This section shall not apply in a case in which the protected health information sought under such discovery request or subpoena—

(1) is nonidentifiable health information;

(2) is related to a party to the litigation whose medical condition is at issue; or

(3) could be disclosed under any of sections 202 through 208, 210, and 212.

(d) EFFECT OF SECTION.—This section shall not be construed to supersede any grounds that may apply under Federal or State law for objecting to turning over the protected health information.

SEC. 210. DISCLOSURE FOR LAW ENFORCEMENT PURPOSES.

(a) IN GENERAL.—A health care provider, health plan, health oversight agency, employer, life insurer, law enforcement official, school, university, or person who receives protected health information pursuant to sections 203 through 208, may disclose protected health information under this section to a law enforcement official con-

ducting or supervising a law enforcement inquiry pursuant to—

(1) a subpoena issued under the authority of a grand jury;

(2) an administrative subpoena or summons pursuant to Federal or State law, or judicial subpoena;

(3) a civil investigative demand pursuant to Federal or State law as issued by the Attorney General or a State official as authorized by State law; new

(4) a warrant issued on a showing of probable cause;

(5) a law requiring the reporting of protected health information to law enforcement officials, including laws requiring the reporting of wounds, rape, or abuse or neglect;

(6) a request otherwise authorized under Federal or State law for the conduct of lawful intelligence activities conducted pursuant to the National Security Act of 1947 (50 U.S.C. 401 et seq.); new

(7) a request made in connection with providing protective services to the President or other individuals pursuant to section 3056 of title 18, United States Code; or new

(7) any other court order.

Nothing in this subsection shall be construed to permit a person to refuse to disclose information on the grounds that such disclosure is not required under this subsection.

(b) DESTRUCTION OR RETURN OF INFORMATION.—When the law enforcement need, investigation or proceeding for which protected health information was disclosed, including matters before a grand jury, has concluded, including any derivative matters which may have arisen from the original need, investigation or proceeding, the law enforcement agency or grand jury shall either destroy the protected health information, or return it to the person from whom it was obtained unless another applicable law ~~(or upon the discretion of the Attorney General)~~ requires that the protected health information be retained by the law enforcement agency, including DNA database entries for sexual offenders. This subsection shall not apply to protected health information disclosed to an entity as provided for under paragraph (6) or (7) of subsection (a).

Unless or the AG determines that such phi should be maintained

(c) REDACTIONS.—A law enforcement agency shall, when necessary to disclose protected health information in public forums (such as court filings or trials, or administrative proceedings, where the individual who is the subject of the protected health information has either not consented to the disclosure, or not put their health condition at issue)—

(1) redact the personally identifiable information to the extent practicable; or

(2) if not practicable, otherwise minimize, in a reasonable and appropriate manner, the public disclosure of protected health information.

(d) USE OF INFORMATION.—Protected health information obtained by a law enforcement agency pursuant to this section may only be used for purposes of a legitimate law enforcement inquiry.

(e) PRISON AND DETENTION FACILITIES.—A person or detention or correctional facility, or a law enforcement agency acting as a detention or correctional facility, that provides health care services to detainees, prisoners or inmates, shall not be subject to the provisions of this Act with respect to the protected health information that is created through the provision of such health care services, so long as such information is used or disclosed only for the purposes of security, safety, corrections, probation, pardon, and parole or as otherwise authorized by Federal or State law or in order to provide health care services for that detainee, prisoner, or inmate.

(f) LIMITATION ON USE AND DISCLOSURE FOR LAW ENFORCEMENT INQUIRIES.—Protected health information about an individual that is disclosed under this section may not be used in any administrative, civil, or crimi-

nal action or investigation directed against the individual, unless the information is relevant to a legitimate law enforcement inquiry or as permitted under subsection (e).

(g) IDENTIFICATION OF INDIVIDUALS.—Notwithstanding subsections (a) and (b), a health care provider may, in response to a law enforcement inquiry, provide the name, address, social security number, date of birth, place of birth, type of injury, and date and time of treatment of an individual who received medical services from the health care provider if obtaining the identity of such individual is necessary for an official law enforcement inquiry.

(h) EXCEPTIONS.—Nothing in this section shall be construed to limit the provisions of section 205 that govern disclosures to a law enforcement official performing an official oversight function that is subject to such section.

SEC. 211. PAYMENT CARD AND ELECTRONIC PAYMENT TRANSACTION.

(a) PAYMENT FOR HEALTH CARE THROUGH CARD OR ELECTRONIC MEANS.—If an individual pays for health care by presenting a debit, credit, or other payment card or account number, or by any other electronic payment means, the entity receiving payment may disclose to a person described in subsection (b) only such protected health