Medical Privacy Bills in the 105th Congress

S. 1368, Leahy - Medical Information Privacy and Security Act (Cosponsor Kennedy)

S. 1921, Jeffords - Health Care Personal Information Nondisclosure Act of 1998 (Cosponsor Dodd)

S. 2609, Bennett - The Medical Information Protection Act of 1998 (Cosponsor Mack)

Preemption of State Law

Leahy -- Federal floor, more protective state laws not pre-empted

Jeffords -- Federal standards pre-empt all state laws, carve outs for public health

Bennett -- Federal standards pre-empt all state laws

Authorization

Leahy -- Prohibits plans/providers from conditioning payment/treatment on authorization, but allows plans not to pay and providers not to treat if patient will not authorize disclosure of the information necessary for such treatment/payment. Result: any disclosure other than treatment or payment will require explicit authorization, and such authorization cannot be a condition of payment/treatment. Authorization expires when person leaves plan, except for uses necessary to complete plan administration related to the individual's period of enrollment.

Jeffords -- Authorization for disclosure for treatment, payment, and health care operations must be obtained as a condition of enrollment (and treatment). Other uses require additional authorization. Allows revocation at any time unless the information is required for payment and the subject has not agreed to assume financial responsibility. Authorization expires when person leaves plan, except for uses necessary to complete health care operations related to the individual's period of enrollment.

Bennett -- Authorization for disclosure for treatment, payment, and health care operations must be obtained as a condition of enrollment (and treatment). *May terminate coverage if not obtained.* Other uses require additional authorization. Allows revocation at any time unless the information is required for payment or treatment or to conduct health care operations for care already provided to the individual. Authorization expires when person leaves plan, except for uses necessary to complete health care operations related to the individual's period of enrollment.

Health Care Operations

Leahy -- Term (health care "administration") not defined

Jeffords -- Definition so expansive as to render authorization meaningless (e.g., phrases such as "management functions of a health plan" and "implementing the terms of a contract for health plan benefits" are not further defined).

Bennett -- Definition so expansive as to render authorization meaningless (e.g., phrase "management functions of a health plan" and "implementing the terms of a contract for health plan benefits" are not further defined).

Research

Leahy -- All research must abide by "Common Rule, " no modifications to Common Rule are included.

Jeffords -- If Congress fails to enact legislation to address private sector research within 2 years after enactment, HHS to write regulations.

Bennett -- Private sector research not covered. Entities enter agreements with researchers detailing acceptable uses of protected health information, no standards for contents of such agreement.

Law Enforcement

Leahy -- Requires court order by court of competent jurisdiction issued only after law enforcement authority demonstrates by clear and convincing evidence that information is necessary to investigate a particular violation, that the need cannot be satisfied by non-identifiable information, and that the law enforcement need outweighs the privacy interests of the individual. (There is an exception for "hot pursuit" and other exigent circumstances.) The individual must be notified in advance and given an opportunity to object, unless the court finds by clear and convincing evidence that the name and address of the individual are unknown or that notice would risk destruction of evidence. Limits sharing the information obtained to actions arising out of or directly related to the law enforcement inquiry for which the information was obtained.

Jeffords -- Covered entities may disclose pursuant to grand jury subpoena, administrative subpoena or summons, or judicial subpoena or warrant or judicial subpoena or a request otherwise authorized by State or Federal law. Incorporates probable cause standard.

Bennett -- Covered entities may disclose pursuant to a grand jury subpoena, or administrative or judicial subpoena or summons, to prevent or prosecute fraud, to report a reasonable belief that illegal activities have been conducted, or pursuant to a request from a law enforcement agency otherwise authorized by Federal or State law.

Oversight

Leahy -- Allows disclosure only of non-identifiable information, and prohibits use of information about an individual against that individual.

Jeffords -- Allows disclosure for oversight. Limits use of disclosed information against the subject individual to actions that arise out of and are directly related to the receipt of care or payment for care, a fraudulent claim related to health care, or an action involving oversight of a public health authority or researcher.

Bennett -- Allows disclosure for oversight. Limits use of disclosed information against the subject individual to actions that arise out of and are directly related to the receipt of care or payment for care, a fraudulent claim related to health care.

Private Right of Action – Leahy and Jeffords, relief limited to equitable and the greater of compensatory or $5000 (and fees), unless the violation was "knowing." (All bills provide for civil and criminal sanctions.)

Scope – All bills apply to employers, schools, and universities outside their capacities as health providers/insurers. All apply to life insurers.

Patient Bill of Rights

Senate - Title I of key bills - related primarily to individuals rights to inspect and copy medical records. Provisions are generally agreed upon.

House bill -- (Thomas) Preemption language very broad - "any person who maintains protected health information . . . " would have preempted any state law that contained restrictions on subsequent disclosures. Therefore, entities could release to newspapers, and would have permitted CVS situation. Managers amendment made it illegal for a plan or provider to 'sell or barter' info. Left open the possibility that it could be given away.

Chris Jennings
EOB 216R

Background Materials for OASIS Meeting at 6:30 p.m. Today

There is a meeting on OASIS at 6:30 p.m. today with HCFA. The purpose of the meeting is to discuss the proper Administration response to recent criticism of the data collection effort. In particular, March 11th Washington Post and New York Times articles raised privacy concerns about the OASIS data and its uses. (See attached.) It is imperative that we flesh out a preliminary position with HCFA since Administrator Nancy-Ann Min DeParle has scheduled a meeting with Congressman Markey (Ma.) tomorrow morning to discuss the Administration's response. Congressman Markey has sponsored a bill that would abolish OASIS.

OMB staff support the OASIS collection in concept as proposed. However, during the last week, HCFA has not been able to adequately defend the OASIS data elements, its privacy protections, and transmission/dissemination plans. In this meeting, OMB staff hope to press HCFA to defend OASIS' data elements and the necessary privacy protections in a more coherent and concerted manner. Improper reaction to press and congressional criticism will establish a harmful precedent for future quality of care and reimbursement initiatives.

Introduction to OASIS

The Medicare/Medicaid Home Health Agency OASIS (Outcome and Assessment Information Set) principally is a patient-specific assessment instrument that is intended to measure patient health outcomes and improve the quality of Medicare/Medicaid home health care. The proposed rules published in March 1997 were a significant component of HCFA's REGO initiative. HCFA also plans to use the OASIS data to construct a case-mix adjusted, home health prospective payment system mandated by the Balanced Budget Act of 1997.

The primary purpose of OASIS is to standardize a minimum core of assessment items. The majority of the OASIS items (19 pages of 79 questions) already are components of HHA resident assessments and medical records. The instrument is expected to displace other routine home health paperwork. The OASIS began with 250 questions and since its inception in the late 1980's, has been streamlined and tested. The Home Health industry generally endorses the substance of OASIS and is most concerned with receiving adequate Medicare reimbursement for its administrative costs. Eventually the OASIS may allow HCFA to better manage its survey and certification process and focus regulation on poor performers.

Privacy Protections

The final regulations and draft Systems of Records notice offer some protections for privacy but do not articulate in detail HCFA's plans for minimizing the privacy risks in transmitting/disseminating individually-identifiable data. From our discussions with HCFA, it appears that they expect to receive all the OASIS data in identifiable form from the state agencies on a continuous basis. OMB staff have

attempted to understand why HCFA needs the universe of these identifiable data to perform basic survey and certification enforcement and PPS development. HCFA has failed to clearly articulate the uses of these personally identifiable data and their intended protections..

Options

HCFA has focused on deleting data elements or their use at the Federal level, while OMB prefers that HCFA better manages its collection, use and dissemination of personal identifiers and its management of the state survey agencies.

HCFA

1. **Transmittal of Public but not Private Data.** HCFA is considering transmitting only Federal patient (Medicare/Medicaid) data up to Baltimore through the state agencies. Private-pay data would remain in the Home Health Agency for its uses in quality improvement activities.

2. **Drastically Streamlined Instrument.** HCFA is considering cutting the survey from 79 to 20 questions. OMB staff are concerned that many of the questions that would be cut are valuable for quality of care and may be necessary to construct a defensible PPS.

OMB

1. **Routine Transmittal to HCFA without Personal Identifiers.** HCFA has failed to justify why it needs all data with personal identifiers to perform its quality of care and PPS functions. OMB believes that HCFA can collect the same OASIS data without identifiers and perform these activities. For certain program integrity functions, HCFA could request data on a case-by-case or HHA-specific basis. HCFA argues that this approach would result in increased transaction load, increased State system capacity, and programming adjustments costing millions of dollars.

2. **Refinements to the Draft Systems of Records Notice.** HCFA may "tighten up" its language in this Notice to more clearly reflect preliminary restrictions on research use, and more incremental disclosures for other functions such as program integrity.

3. **Sampling.** It may be possible to reduce the burden on HHAs and reduce risk to privacy by using sampling techniques, particularly for research and audit/program integrity functions However, historically HCFA has had difficulty defending sampling for HHA program integrity and must improve its design and implementation of these policies.

WP: U.S. to Start Gathering Patient Data Care Survey Draws Privacy Objections
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By Robert O'Harrow Jr.
Washington Post Staff Writer
Thursday, March 11, 1999; Page A01

Federal officials will soon begin collecting personal information about millions of homebound patients -- including details about their mental stability, financial status and living arrangements -- in an effort to improve service in the home health care industry.

The Health Care Financing Administration, which oversees Medicare and Medicaid, believes the new database will help federal and state authorities better track the performance of more than 9,000 home health care providers certified by Medicare.

Agency officials said analysts will use information drawn from the questions to determine if home health care companies are providing the proper response to patient problems.

Agency officials also intend to use the data to ensure Medicare pays the same amount for similar services across the country. As the home health care industry experienced rapid growth over the past decade, federal investigators found inflated billing and questionable medical practices had become common.

In addition to patients' names and addresses and a series of questions about medical conditions, the 19-page assessment asks whether patients are depressed or feel a "sense of failure." It asks if patients have attempted suicide, exhibited "socially inappropriate behavior" or made any "sexual references" during conversations. It also touches on personal finances, such as whether a patient is "unable to afford rent/utility bills." Transmission of the data will begin next month.

While HCFA maintains huge amounts of medical data about patients who receive federal benefits, the new survey includes questions that delve more deeply into patients' personal lives, according to Janlori Goldman, director of the Health Privacy Project at Georgetown University.

"There has to be a way to check fraud and abuse without intruding on patient privacy. . . . There's a tremendous risk of abuse that the information will be used for other purposes," Goldman said. "It's truly a coerced collection of information."

Civil liberties activists also said they were concerned that health care providers now will be required to compile and send along details about all patients they serve, not just those who receive federal benefits. Industry officials estimate that more than 4 million patients receive services through home care companies.

Other critics include the Home Health Services and Staffing Association, an industry group that has complained about the cost of complying with the program, and the American Psychiatric Association, which objects to questions involving mental health.

"There is no requirement that patients would be asked for their voluntary, informed consent before answering any questions," the psychiatric association said in a letter to the agency.

Even strong supporters of the plan -- such as Rep. Fortney "Pete" Stark (D-Calif.), who believes it will improve care -- have balked at what patients will be asked. "Are they to be informed that this information, including their names, will be disclosed to their state government and the federal government?" Stark asked in a letter to the agency.

Sen. Patrick J. Leahy (D-Vt.), who introduced a bill yesterday that would strengthen rules governing the confidentiality of medical records, said the effort demonstrates the need for stronger privacy laws. "The marriage of information technology with privacy rights needs a rule book that hasn't been written yet," Leahy said. "It is becoming easier to dig deeply into anyone's health and financial and personal information, and no one is there to tap the brakes "

But HCFA officials said the detailed questions in the Outcome and Assessment Information Set, or OASIS, will enable them to "promote higher quality care." It also will help the agency -- part of the Department of Health and Human Services -- to reduce fraud and inconsistent billing, as Congress mandated in the Balanced Budget Act of 1997.

Under rules that took effect in February, home health care providers will be required to conduct the survey when enrolling a new patient and then every 60 days until services conclude. The data will be sent electronically to computers at the state agencies that oversee the operation of the health care companies. Then it will be sent to databases maintained by HCFA.

"We want beneficiaries who qualify for the home health benefit to get the best care and Medicare to pay appropriately," agency administrator Nancy-Ann Min DeParle said in a January statement. "This new patient assessment information will help Medicare both ways."

Agency officials said they needed to collect data about patients who don't receive federal benefits because they have a legal obligation to ensure the

same quality of care for all patients. Patients will be notified what information is being gathered and how it will be used, officials said.

Officials also said access to the data will be extremely limited in accordance with existing federal privacy regulations. Chris Peacock, an agency spokesman, said medical researchers will not be allowed to see any identifiable information. Other government agencies will not be permitted to access the database, Peacock said.

"It's secure at all times, and access is strictly limited," Peacock said. The agency "consistently safeguards confidential information."

But critics said the government doesn't need to collect some of the information it requires.

"Whether you're depressed or not is not information you should have to disclose to a government agency," said Denise Nagel, executive director of the National Coalition for Patient Rights, a nonprofit advocacy group.

Outcome and Assessment Information Set (OASIS-B1)

According to the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0938-XXXX. The time required to complete this information collection is estimated to average 31 minutes per response including the time to review instructions, search existing data resources, gather the data needed, and complete and review the information collection. If you have any comments concerning the accuracy of the time estimate(s) or suggestions for improving this form, please write to: HCFA, 7500 Security Boulevard, Baltimore, Maryland 21244-1850, Mail Stop N2-14-26 and to the Office and Management and Budget, Washington, D.C. 20503.

This data set should not be reviewed or used without first reading the accompanying narrative prologue that explains the purpose of the OASIS and its past and planned evolution.

Items to be Used at Specific Time Points

Start or Resumption of Care ---------------------- M0010-M0820

- Start of care—further visits planned
- Start of care—no further visits planned
- Resumption of care (after inpatient stay)

Follow-Up ---------------------------------- M0010-M0100, M0150, M0200-M0220, M0250, M0280-M0380, M0410-M0840

- Recertification (follow-up) assessment
- Other follow-up assessment

Transfer to an Inpatient Facility -------------------- M0010-M0100, M0830-M0855, M0890-M0906

- Transferred to an inpatient facility—patient not discharged from an agency
- Transferred to an inpatient facility—patient discharged from agency

Discharge from Agency — Not to an Inpatient Facility

- Death at home ------------------------------ M0010-M0100, M0906
- Discharge from agency ------------------------ M0010-M0100, M0150, M0200-M0220, M0250, M0280-M0380, M0410-M0880, M0903-M0906
- Discharge from agency—no visits completed after start/resumption of care assessment ----------- M0010-M0100, M0906

Note: For items M0640-M0800, please note special instructions at the beginning of the section.

CLINICAL RECORD ITEMS

(M0010) Agency Medicare Provider Number: _ _ _ _ _ _

(M0012) Agency Medicaid Provider Number: _ _ _ _ _ _ _ _ _ _ _ _ _ _

Branch Identification (Optional, for Agency Use)

(M0014) Branch State: _ _

(M0016) Branch ID Number: _ _ _ _ _ _ _ _ _ _
(Agency-assigned)

(M0020) Patient ID Number: _

(M0030) Start of Care Date: _ _ /_ _ /_ _ _ _
month day year

(M0032) Resumption of Care Date: _ _ /_ _ /_ _ _ _
month day year
☐ **NA – Not Applicable**

(M0040) Patient Name:

_ _
(First) (MI) (Last) (Suffix)

(M0050) **Patient State of Residence:** ___

(M0060) **Patient Zip Code:** _____ _____

(M0063) **Medicare Number:** _____ ☐ **NA – No Medicare**
(including suffix)

(M0064) **Social Security Number:** ___-___-_____ ☐ **UK – Unknown or Not Available**

(M0065) **Medicaid Number:** _____ ☐ **NA – No Medicaid**

(M0066) **Birth Date:** ___/___/_____
month day year

(M0069) **Gender:**

☐ 1 - Male
☐ 2 - Female

(M0072) **Primary Referring Physician ID:**

_____ ☐ **UK – Unknown or Not Available**

(M0080) **Discipline of Person Completing Assessment:**

☐ 1-RN ☐ 2-PT ☐ 3-SLP/ST ☐ 4-OT

(M0090) **Date Assessment Completed:** ___/___/_____
month day year

(M0100) **This Assessment is Currently Being Completed for the Following Reason:**

Start/Resumption of Care
☐ 1 – Start of care—further visits planned
☐ 2 – Start of care—no further visits planned
☐ 3 – Resumption of care (after inpatient stay)

Follow-Up
☐ 4 – Recertification (follow-up) reassessment **[Go to *M0150*]**
☐ 5 – Other follow-up **[Go to *M0150*]**

Transfer to an Inpatient Facility
☐ 6 – Transferred to an inpatient facility—patient not discharged from agency **[Go to *M0830*]**
☐ 7 – Transferred to an inpatient facility—patient discharged from agency **[Go to *M0830*]**

Discharge from Agency — Not to an Inpatient Facility
☐ 8 – Death at home **[Go to *M0906*]**
☐ 9 – Discharge from agency **[Go to *M0150*]**
☐ 10 – Discharge from agency—no visits completed after start/resumption of care assessment **[Go to *M0906*]**

DEMOGRAPHICS AND PATIENT HISTORY

(M0140) **Race/Ethnicity** (as identified by patient): **(Mark all that apply.)**

☐ 1 - American Indian or Alaska Native
☐ 2 - Asian
☐ 3 - Black or African-American
☐ 4 - Hispanic or Latino
☐ 5 - Native Hawaiian or Pacific Islander
☐ 6 - White
☐ UK - Unknown

(M0150) Current Payment Sources for Home Care: (Mark all that apply.)

- ☐ 0 - None; no charge for current services
- ☐ 1 - Medicare (traditional fee-for-service)
- ☐ 2 - Medicare (HMO/managed care)
- ☐ 3 - Medicaid (traditional fee-for-service)
- ☐ 4 - Medicaid (HMO/managed care)
- ☐ 5 - Workers' compensation
- ☐ 6 - Title programs (e.g., Title III, V, or XX)
- ☐ 7 - Other government (e.g., CHAMPUS, VA, etc.)
- ☐ 8 - Private insurance
- ☐ 9 - Private HMO/managed care
- ☐ 10 - Self-pay
- ☐ 11 - Other (specify)
- ☐ UK - Unknown

(M0160) Financial Factors limiting the ability of the patient/family to meet basic health needs: **(Mark all that apply.)**

- ☐ 0 - None
- ☐ 1 - Unable to afford medicine or medical supplies
- ☐ 2 - Unable to afford medical expenses that are not covered by insurance/Medicare (e.g., copayments)
- ☐ 3 - Unable to afford rent/utility bills
- ☐ 4 - Unable to afford food
- ☐ 5 - Other (specify)

(M0170) From which of the following **Inpatient Facilities** was the patient discharged during the past 14 days? **(Mark all that apply.)**

- ☐ 1 - Hospital
- ☐ 2 - Rehabilitation facility
- ☐ 3 - Nursing home
- ☐ 4 - Other (specify)
- ☐ NA - Patient was not discharged from an inpatient facility **[If NA, go to *M0200*]**

(M0180) Inpatient Discharge Date (most recent):

__ __ / __ __ / __ __ __ __
month day year

- ☐ UK - Unknown

(M0190) Inpatient Diagnoses and ICD code categories (three digits required; five digits optional) for only those conditions treated during an inpatient facility stay within the last 14 days (no surgical or V-codes):

	Inpatient Facility Diagnosis	ICD
a.	_____	(__ __ __ . __ __)
b.	_____	(__ __ __ . __ __)

(M0200) Medical or Treatment Regimen Change Within Past 14 Days: Has this patient experienced a change in medical or treatment regimen (e.g., medication, treatment, or service change due to new or additional diagnosis, etc.) within the last 14 days?

- ☐ 0 - No **[If No, go to *M0220*]**
- ☐ 1 - Yes

(M0210) List the patient's **Medical Diagnoses** and ICD code categories (three digits required; five digits optional) for those conditions requiring changed medical or treatment regimen (no surgical or V-codes):

	Changed Medical Regimen Diagnosis	ICD
a.	_____	(___.__)
b.	_____	(___.__)
c.	_____	(___.__)
d.	_____	(___.__)

(M0220) **Conditions Prior to Medical or Treatment Regimen Change or Inpatient Stay Within Past 14 Days**: If this patient experienced an inpatient facility discharge or change in medical or treatment regimen within the past 14 days, indicate any conditions which existed prior to the inpatient stay or change in medical or treatment regimen. **(Mark all that apply.)**

- ☐ 1 - Urinary incontinence
- ☐ 2 - Indwelling/suprapubic catheter
- ☐ 3 - Intractable pain
- ☐ 4 - Impaired decision-making
- ☐ 5 - Disruptive or socially inappropriate behavior
- ☐ 6 - Memory loss to the extent that supervision required
- ☐ 7 - None of the above
- ☐ NA - No inpatient facility discharge and no change in medical or treatment regimen in past 14 days
- ☐ UK - Unknown

(M0230/M0240) **Diagnoses and Severity Index**: List each medical diagnosis or problem for which the patient is receiving home care and ICD code category (three digits required; five digits optional – no surgical or V-codes) and rate them using the following severity index. (Choose one value that represents the most severe rating appropriate for each diagnosis.)

0 - Asymptomatic, no treatment needed at this time
1 - Symptoms well controlled with current therapy
2 - Symptoms controlled with difficulty, affecting daily functioning; patient needs ongoing monitoring
3 - Symptoms poorly controlled, patient needs frequent adjustment in treatment and dose monitoring
4 - Symptoms poorly controlled, history of rehospitalizations

	(M0230) Primary Diagnosis	ICD	Severity Rating
a.	_____	(___.__)	☐0 ☐1 ☐2 ☐3 ☐4
	(M0240) Other Diagnoses	ICD	Severity Rating
b.	_____	(___.__)	☐0 ☐1 ☐2 ☐3 ☐4
c.	_____	(___.__)	☐0 ☐1 ☐2 ☐3 ☐4
d.	_____	(___.__)	☐0 ☐1 ☐2 ☐3 ☐4
e.	_____	(___.__)	☐0 ☐1 ☐2 ☐3 ☐4
f.	_____	(___.__)	☐0 ☐1 ☐2 ☐3 ☐4

(M0250) **Therapies** the patient receives at home: **(Mark all that apply.)**

- ☐ 1 - Intravenous or infusion therapy (excludes TPN)
- ☐ 2 - Parenteral nutrition (TPN or lipids)
- ☐ 3 - Enteral nutrition (nasogastric, gastrostomy, jejunostomy, or any other artificial entry into the alimentary canal)
- ☐ 4 - None of the above

(M0260) Overall Prognosis: BEST description of patient's overall prognosis for recovery from this episode of illness.

- ☐ 0 - Poor: little or no recovery is expected and/or further decline is imminent
- ☐ 1 - Good/Fair: partial to full recovery is expected
- ☐ UK - Unknown

(M0270) Rehabilitative Prognosis: BEST description of patient's prognosis for functional status.

- ☐ 0 - Guarded: minimal improvement in functional status is expected; decline is possible
- ☐ 1 - Good: marked improvement in functional status is expected
- ☐ UK - Unknown

(M0280) Life Expectancy: (Physician documentation is not required.)

- ☐ 0 - Life expectancy is greater than 6 months
- ☐ 1 - Life expectancy is 6 months or fewer

(M0290) High Risk Factors characterizing this patient: **(Mark all that apply.)**

- ☐ 1 - Heavy smoking
- ☐ 2 - Obesity
- ☐ 3 - Alcohol dependency
- ☐ 4 - Drug dependency
- ☐ 5 - None of the above
- ☐ UK - Unknown

LIVING ARRANGEMENTS

(M0300) Current Residence:

- ☐ 1 - Patient's owned or rented residence (house, apartment, or mobile home owned or rented by patient/couple/significant other)
- ☐ 2 - Family member's residence
- ☐ 3 - Boarding home or rented room
- ☐ 4 - Board and care or assisted living facility
- ☐ 5 - Other (specify)

(M0310) Structural Barriers in the patient's environment limiting independent mobility: **(Mark all that apply.)**

- ☐ 0 - None
- ☐ 1 - Stairs inside home which must be used by the patient (e.g., to get to toileting, sleeping, eating areas)
- ☐ 2 - Stairs inside home which are used optionally (e.g., to get to laundry facilities)
- ☐ 3 - Stairs leading from inside house to outside
- ☐ 4 - Narrow or obstructed doorways

(M0320) Safety Hazards found in the patient's current place of residence: **(Mark all that apply.)**

- ☐ 0 - None
- ☐ 1 - Inadequate floor, roof, or windows
- ☐ 2 - Inadequate lighting
- ☐ 3 - Unsafe gas/electric appliance
- ☐ 4 - Inadequate heating
- ☐ 5 - Inadequate cooling
- ☐ 6 - Lack of fire safety devices
- ☐ 7 - Unsafe floor coverings
- ☐ 8 - Inadequate stair railings
- ☐ 9 - Improperly stored hazardous materials
- ☐ 10 - Lead-based paint
- ☐ 11 - Other (specify)

(M0330) Sanitation Hazards found in the patient's current place of residence: **(Mark all that apply.)**

- ☐ 0 - None
- ☐ 1 - No running water
- ☐ 2 - Contaminated water
- ☐ 3 - No toileting facilities
- ☐ 4 - Outdoor toileting facilities only
- ☐ 5 - Inadequate sewage disposal
- ☐ 6 - Inadequate/improper food storage
- ☐ 7 - No food refrigeration
- ☐ 8 - No cooking facilities
- ☐ 9 - Insects/rodents present
- ☐ 10 - No scheduled trash pickup
- ☐ 11 - Cluttered/soiled living area
- ☐ 12 - Other (specify)

(M0340) Patient Lives With: (Mark all that apply.)

- ☐ 1 - Lives alone
- ☐ 2 - With spouse or significant other
- ☐ 3 - With other family member
- ☐ 4 - With a friend
- ☐ 5 - With paid help (other than home care agency staff)
- ☐ 6 - With other than above

SUPPORTIVE ASSISTANCE

(M0350) Assisting Person(s) Other than Home Care Agency Staff: (Mark all that apply.)

- ☐ 1 - Relatives, friends, or neighbors living outside the home
- ☐ 2 - Person residing in the home (EXCLUDING paid help)
- ☐ 3 - Paid help
- ☐ 4 - None of the above **[If None of the above, go to *M0390*]**
- ☐ UK - Unknown **[If Unknown, go to *M0390*]**

(M0360) **Primary Caregiver** taking lead responsibility for providing or managing the patient's care, providing the most frequent assistance, etc. (other than home care agency staff):

- ☐ 0 - No one person **[If No one person, go to *M0390*]**
- ☐ 1 - Spouse or significant other
- ☐ 2 - Daughter or son
- ☐ 3 - Other family member
- ☐ 4 - Friend or neighbor or community or church member
- ☐ 5 - Paid help
- ☐ UK - Unknown **[If Unknown, go to *M0390*]**

(M0370) **How Often** does the patient receive assistance from the primary caregiver?

- ☐ 1 - Several times during day and night
- ☐ 2 - Several times during day
- ☐ 3 - Once daily
- ☐ 4 - Three or more times per week
- ☐ 5 - One to two times per week
- ☐ 6 - Less often than weekly
- ☐ UK - Unknown

(M0380) **Type of Primary Caregiver Assistance: (Mark all that apply.)**

- ☐ 1 - ADL assistance (e.g., bathing, dressing, toileting, bowel/bladder, eating/feeding)
- ☐ 2 - IADL assistance (e.g., meds, meals, housekeeping, laundry, telephone, shopping, finances)
- ☐ 3 - Environmental support (housing, home maintenance)
- ☐ 4 - Psychosocial support (socialization, companionship, recreation)
- ☐ 5 - Advocates or facilitates patient's participation in appropriate medical care
- ☐ 6 - Financial agent, power of attorney, or conservator of finance
- ☐ 7 - Health care agent, conservator of person, or medical power of attorney
- ☐ UK - Unknown

SENSORY STATUS

(M0390) **Vision** with corrective lenses if the patient usually wears them:

- ☐ 0 - Normal vision: sees adequately in most situations; can see medication labels, newsprint.
- ☐ 1 - Partially impaired: cannot see medication labels or newsprint, but can see obstacles in path, and the surrounding layout; can count fingers at arm's length.
- ☐ 2 - Severely impaired: cannot locate objects without hearing or touching them or patient nonresponsive.

(M0400) **Hearing and Ability to Understand Spoken Language** in patient's own language (with hearing aids if the patient usually uses them):

- ☐ 0 - No observable impairment. Able to hear and understand complex or detailed instructions and extended or abstract conversation.
- ☐ 1 - With minimal difficulty, able to hear and understand most multi-step instructions and ordinary conversation. May need occasional repetition, extra time, or louder voice.
- ☐ 2 - Has moderate difficulty hearing and understanding simple, one-step instructions and brief conversation; needs frequent prompting or assistance.
- ☐ 3 - Has severe difficulty hearing and understanding simple greetings and short comments. Requires multiple repetitions, restatements, demonstrations, additional time.
- ☐ 4 - Unable to hear and understand familiar words or common expressions consistently, or patient nonresponsive.

(M0410) Speech and Oral (Verbal) Expression of Language (in patient's own language):

- ☐ 0 - Expresses complex ideas, feelings, and needs clearly, completely, and easily in all situations with no observable impairment.
- ☐ 1 - Minimal difficulty in expressing ideas and needs (may take extra time; makes occasional errors in word choice, grammar or speech intelligibility; needs minimal prompting or assistance).
- ☐ 2 - Expresses simple ideas or needs with moderate difficulty (needs prompting or assistance, errors in word choice, organization or speech intelligibility). Speaks in phrases or short sentences.
- ☐ 3 - Has severe difficulty expressing basic ideas or needs and requires maximal assistance or guessing by listener. Speech limited to single words or short phrases.
- ☐ 4 - Unable to express basic needs even with maximal prompting or assistance but is not comatose or unresponsive (e.g., speech is nonsensical or unintelligible).
- ☐ 5 - Patient nonresponsive or unable to speak.

(M0420) Frequency of Pain interfering with patient's activity or movement:

- ☐ 0 - Patient has no pain or pain does not interfere with activity or movement
- ☐ 1 - Less often than daily
- ☐ 2 - Daily, but not constantly
- ☐ 3 - All of the time

(M0430) Intractable Pain: Is the patient experiencing pain that is not easily relieved, occurs at least daily, and affects the patient's sleep, appetite, physical or emotional energy, concentration, personal relationships, emotions, or ability or desire to perform physical activity?

- ☐ 0 - No
- ☐ 1 - Yes

INTEGUMENTARY STATUS

(M0440) Does this patient have a **Skin Lesion** or an **Open Wound?** This excludes "OSTOMIES."

- ☐ 0 - No **[If No, go to *M0490*]**
- ☐ 1 - Yes

(M0445) Does this patient have a **Pressure Ulcer**?

- ☐ 0 - No **[If No, go to *M0468*]**
- ☐ 1 - Yes

(M0450) Current Number of Pressure Ulcers at Each Stage: (Circle one response for each stage.)

	Pressure Ulcer Stages	Number of Pressure Ulcers				
a)	Stage 1: Nonblanchable erythema of intact skin; the heralding of skin ulceration. In darker-pigmented skin, warmth, edema, hardness, or discolored skin may be indicators.	0	1	2	3	4 or more
b)	Stage 2: Partial thickness skin loss involving epidermis and/or dermis. The ulcer is superficial and presents clinically as an abrasion, blister, or shallow crater.	0	1	2	3	4 or more
c)	Stage 3: Full-thickness skin loss involving damage or necrosis of subcutaneous tissue which may extend down to, but not through, underlying fascia. The ulcer presents clinically as a deep crater with or without undermining of adjacent tissue.	0	1	2	3	4 or more
d)	Stage 4: Full-thickness skin loss with extensive destruction, tissue necrosis, or damage to muscle, bone, or supporting structures (e.g., tendon, joint capsule, etc.)	0	1	2	3	4 or more
e)	In addition to the above, is there at least one pressure ulcer that cannot be observed due to the presence of eschar or a nonremovable dressing, including casts? ☐ 0 - No ☐ 1 - Yes					

(M0460) Stage of Most Problematic (Observable) Pressure Ulcer:

- ☐ 1 - Stage 1
- ☐ 2 - Stage 2
- ☐ 3 - Stage 3
- ☐ 4 - Stage 4
- ☐ NA - No observable pressure ulcer

(M0464) Status of Most Problematic (Observable) Pressure Ulcer:

- ☐ 1 - Fully granulating
- ☐ 2 - Early/partial granulation
- ☐ 3 - Not healing
- ☐ NA - No observable pressure ulcer

(M0468) Does this patient have a **Stasis Ulcer**?

- ☐ 0 - No **[If No, go to *M0482*]**
- ☐ 1 - Yes

(M0470) Current Number of Observable Stasis Ulcer(s):

- ☐ 0 - Zero
- ☐ 1 - One
- ☐ 2 - Two
- ☐ 3 - Three
- ☐ 4 - Four or more

(M0474) Does this patient have at least one **Stasis Ulcer that Cannot be Observed** due to the presence of a nonremovable dressing?

- ☐ 0 - No
- ☐ 1 - Yes

(M0476) Status of Most Problematic (Observable) Stasis Ulcer:

- ☐ 1 - Fully granulating
- ☐ 2 - Early/partial granulation
- ☐ 3 - Not healing
- ☐ NA - No observable stasis ulcer

(M0482) Does this patient have a **Surgical Wound?**

- ☐ 0 - No **[If No, go to *M0490*]**
- ☐ 1 - Yes

(M0484) Current Number of (Observable) Surgical Wounds: (If a wound is partially closed but has more than one opening, consider each opening as a separate wound.)

- ☐ 0 - Zero
- ☐ 1 - One
- ☐ 2 - Two
- ☐ 3 - Three
- ☐ 4 - Four or more

(M0486) Does this patient have at least one **Surgical Wound that Cannot be Observed** due to the presence of a nonremovable dressing?

- ☐ 0 - No
- ☐ 1 - Yes

(M0488) Status of Most Problematic (Observable) Surgical Wound:

- ☐ 1 - Fully granulating
- ☐ 2 - Early/partial granulation
- ☐ 3 - Not healing
- ☐ NA - No observable surgical wound

RESPIRATORY STATUS

(M0490) When is the patient dyspneic or noticeably **Short of Breath**?

- ☐ 0 - Never, patient is not short of breath
- ☐ 1 - When walking more than 20 feet, climbing stairs
- ☐ 2 - With moderate exertion (e.g., while dressing, using commode or bedpan, walking distances less than 20 feet)
- ☐ 3 - With minimal exertion (e.g., while eating, talking, or performing other ADLs) or with agitation
- ☐ 4 - At rest (during day or night)

(M0500) Respiratory Treatments utilized at home: **(Mark all that apply.)**

- ☐ 1 - Oxygen (intermittent or continuous)
- ☐ 2 - Ventilator (continually or at night)
- ☐ 3 - Continuous positive airway pressure
- ☐ 4 - None of the above

ELIMINATION STATUS

(M0510) Has this patient been treated for a **Urinary Tract Infection** in the past 14 days?

- ☐ 0 - No
- ☐ 1 - Yes
- ☐ NA - Patient on prophylactic treatment
- ☐ UK - Unknown

(M0520) Urinary Incontinence or Urinary Catheter Presence:

- ☐ 0 - No incontinence or catheter (includes anuria or ostomy for urinary drainage) **[If No, go to *M0540*]**
- ☐ 1 - Patient is incontinent
- ☐ 2 - Patient requires a urinary catheter (i.e., external, indwelling, intermittent, suprapubic) **[Go to *M0540*]**

(M0530) When does **Urinary Incontinence** occur?

- ☐ 0 - Timed-voiding defers incontinence
- ☐ 1 - During the night only
- ☐ 2 - During the day and night

(M0540) Bowel Incontinence Frequency:

- ☐ 0 - Very rarely or never has bowel incontinence
- ☐ 1 - Less than once weekly
- ☐ 2 - One to three times weekly
- ☐ 3 - Four to six times weekly
- ☐ 4 - On a daily basis
- ☐ 5 - More often than once daily
- ☐ NA - Patient has ostomy for bowel elimination
- ☐ UK - Unknown

(M0550) Ostomy for Bowel Elimination: Does this patient have an ostomy for bowel elimination that (within the last 14 days): a) was related to an inpatient facility stay, or b) necessitated a change in medical or treatment regimen?

- ☐ 0 - Patient does not have an ostomy for bowel elimination.
- ☐ 1 - Patient's ostomy was not related to an inpatient stay and did not necessitate change in medical or treatment regimen.
- ☐ 2 - The ostomy was related to an inpatient stay or did necessitate change in medical or treatment regimen.

NEURO/EMOTIONAL/BEHAVIORAL STATUS

(M0560) Cognitive Functioning: (Patient's current level of alertness, orientation, comprehension, concentration, and immediate memory for simple commands.)

- ☐ 0 - Alert/oriented, able to focus and shift attention, comprehends and recalls task directions independently.
- ☐ 1 - Requires prompting (cuing, repetition, reminders) only under stressful or unfamiliar conditions.
- ☐ 2 - Requires assistance and some direction in specific situations (e.g., on all tasks involving shifting of attention), or consistently requires low stimulus environment due to distractibility.
- ☐ 3 - Requires considerable assistance in routine situations. Is not alert and oriented or is unable to shift attention and recall directions more than half the time.
- ☐ 4 - Totally dependent due to disturbances such as constant disorientation, coma, persistent vegetative state, or delirium.

(M0570) When Confused (Reported or Observed):

- ☐ 0 - Never
- ☐ 1 - In new or complex situations only
- ☐ 2 - On awakening or at night only
- ☐ 3 - During the day and evening, but not constantly
- ☐ 4 - Constantly
- ☐ NA - Patient nonresponsive

(M0580) When Anxious (Reported or Observed):

- ☐ 0 - None of the time
- ☐ 1 - Less often than daily
- ☐ 2 - Daily, but not constantly
- ☐ 3 - All of the time
- ☐ NA - Patient nonresponsive

(M0590) Depressive Feelings Reported or Observed in Patient: (Mark all that apply.)

- ☐ 1 - Depressed mood (e.g., feeling sad, tearful)
- ☐ 2 - Sense of failure or self reproach
- ☐ 3 - Hopelessness
- ☐ 4 - Recurrent thoughts of death
- ☐ 5 - Thoughts of suicide
- ☐ 6 - None of the above feelings observed or reported

(M0600) Patient Behaviors (Reported or Observed): (Mark all that apply.)

- ☐ 1 - Indecisiveness, lack of concentration
- ☐ 2 - Diminished interest in most activities
- ☐ 3 - Sleep disturbances
- ☐ 4 - Recent change in appetite or weight
- ☐ 5 - Agitation
- ☐ 6 - A suicide attempt
- ☐ 7 - None of the above behaviors observed or reported

(M0610) Behaviors Demonstrated at Least Once a Week (Reported or Observed): (Mark all that apply.)

- ☐ 1 - Memory deficit: failure to recognize familiar persons/places, inability to recall events of past 24 hours, significant memory loss so that supervision is required
- ☐ 2 - Impaired decision-making: failure to perform usual ADLs or IADLs, inability to appropriately stop activities, jeopardizes safety through actions
- ☐ 3 - Verbal disruption: yelling, threatening, excessive profanity, sexual references, etc.
- ☐ 4 - Physical aggression: aggressive or combative to self and others (e.g., hits self, throws objects, punches, dangerous maneuvers with wheelchair or other objects)
- ☐ 5 - Disruptive, infantile, or socially inappropriate behavior (**excludes** verbal actions)
- ☐ 6 - Delusional, hallucinatory, or paranoid behavior
- ☐ 7 - None of the above behaviors demonstrated

(M0620) Frequency of Behavior Problems (Reported or Observed) (e.g., wandering episodes, self abuse, verbal disruption, physical aggression, etc.):

- ☐ 0 - Never
- ☐ 1 - Less than once a month
- ☐ 2 - Once a month
- ☐ 3 - Several times each month
- ☐ 4 - Several times a week
- ☐ 5 - At least daily

(M0630) Is this patient receiving **Psychiatric Nursing Services** at home provided by a qualified psychiatric nurse?

- ☐ 0 - No
- ☐ 1 - Yes

ADL/IADLs

For M0640-M0800, complete the "Current" column for all patients. For these same items, complete the "Prior" column only at start of care and at resumption of care; mark the level that corresponds to the patient's condition 14 days prior to start of care date (M0030) or resumption of care date (M0032). In all cases, record what the patient is *able to do*.

(M0640) Grooming: Ability to tend to personal hygiene needs (i.e., washing face and hands, hair care, shaving or make up, teeth or denture care, fingernail care).

Prior	Current		
☐	☐	0 -	Able to groom self unaided, with or without the use of assistive devices or adapted methods.
☐	☐	1 -	Grooming utensils must be placed within reach before able to complete grooming activities.
☐	☐	2 -	Someone must assist the patient to groom self.
☐	☐	3 -	Patient depends entirely upon someone else for grooming needs.
☐		UK -	Unknown

(M0650) Ability to Dress Upper Body (with or without dressing aids) including undergarments, pullovers, front-opening shirts and blouses, managing zippers, buttons, and snaps:

Prior	Current		
☐	☐	0 -	Able to get clothes out of closets and drawers, put them on and remove them from the upper body without assistance.
☐	☐	1 -	Able to dress upper body without assistance if clothing is laid out or handed to the patient.
☐	☐	2 -	Someone must help the patient put on upper body clothing.
☐	☐	3 -	Patient depends entirely upon another person to dress the upper body.
☐		UK -	Unknown

(M0660) Ability to Dress Lower Body (with or without dressing aids) including undergarments, slacks, socks or nylons, shoes:

Prior	Current		
☐	☐	0 -	Able to obtain, put on, and remove clothing and shoes without assistance.
☐	☐	1 -	Able to dress lower body without assistance if clothing and shoes are laid out or handed to the patient.
☐	☐	2 -	Someone must help the patient put on undergarments, slacks, socks or nylons, and shoes.
☐	☐	3 -	Patient depends entirely upon another person to dress lower body.
☐		UK -	Unknown

(M0670) Bathing: Ability to wash entire body. **Excludes grooming (washing face and hands only).**

Prior	Current		
☐	☐	0 -	Able to bathe self in shower or tub independently.
☐	☐	1 -	With the use of devices, is able to bathe self in shower or tub independently.
☐	☐	2 -	Able to bathe in shower or tub with the assistance of another person: (a) for intermittent supervision or encouragement or reminders, OR (b) to get in and out of the shower or tub, OR (c) for washing difficult to reach areas.
☐	☐	3 -	Participates in bathing self in shower or tub, but requires presence of another person throughout the bath for assistance or supervision.
☐	☐	4 -	Unable to use the shower or tub and is bathed in bed or bedside chair.
☐	☐	5 -	Unable to effectively participate in bathing and is totally bathed by another person.
☐		UK -	Unknown

(M0680) Toileting: Ability to get to and from the toilet or bedside commode.

Prior	Current		
☐	☐	0 -	Able to get to and from the toilet independently with or without a device.
☐	☐	1 -	When reminded, assisted, or supervised by another person, able to get to and from the toilet.
☐	☐	2 -	Unable to get to and from the toilet but is able to use a bedside commode (with or without assistance).
☐	☐	3 -	Unable to get to and from the toilet or bedside commode but is able to use a bedpan/urinal independently.
☐	☐	4 -	Is totally dependent in toileting.
☐		UK -	Unknown

(M0690) Transferring: Ability to move from bed to chair, on and off toilet or commode, into and out of tub or shower, and ability to turn and position self in bed if patient is bedfast.

Prior	Current		
☐	☐	0 -	Able to independently transfer.
☐	☐	1 -	Transfers with minimal human assistance or with use of an assistive device.
☐	☐	2 -	Unable to transfer self but is able to bear weight and pivot during the transfer process.
☐	☐	3 -	Unable to transfer self and is unable to bear weight or pivot when transferred by another person.
☐	☐	4 -	Bedfast, unable to transfer but is able to turn and position self in bed.
☐	☐	5 -	Bedfast, unable to transfer and is unable to turn and position self.
☐		UK -	Unknown

EDWARD J. MARKEY
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March 24, 1999

Nancy-Ann Min De Parle
Administrator
Health Care Financing Administration
200 Independence Avenue, SW
Washington, DC 20201

Dear Administrator De Parle:

I would like to thank you and your staff for meeting with me yesterday to discuss the privacy concerns that I have regarding the Outcome and Assessment Information Set (OASIS) program. As you know, OASIS is designed to create a standardized assessment for home health agencies to be implemented by April 26, 1999. I realize the importance of this program in assessing quality of care for our most vulnerable population and for implementing the Prospective Payment System by October of 2000 and I appreciated the opportunity to share my concerns with you.

As I first indicated to you by phone last week, one of my primary concerns is that through OASIS, data of a very sensitive and personal nature, will be collected from every home health patient (both Medicare and non-Medicare) served by a Medicare certified home health agency and reported in a fully identifiable form to the State and to the Federal government, where it will be kept in a national data bank. I was encouraged to learn in our meeting yesterday, however, that since our phone conversation, HCFA has reconsidered it's policy on collecting this information in identifiable form from non-Medicare patients. I am pleased with this decision and hope that HCFA will now consider how to accomplish its goals by collecting information on Medicare patients in deidentified form as well.

Furthermore I would like to reiterate my additional and continued concerns:

1. Will patients be informed explicitly what information is to be assessed, by whom this assessment will be made and for what purpose?

2. Will patients (both Medicare and non-Medicare) be given an opportunity to refuse to consent to the collection and reporting of information that is unrelated to their treatment without losing their home health services?

3. Will patients have an opportunity (and be made aware of this opportunity) to view their assessments before they are sent to the State and Federal government? And in the event that they disagree with an assessment will they have the opportunity to correct their information?

4. This information is to be collected for both quality assurance and payment purposes. HCFA maintains that it is necessary to be collected in identified form for payment purposes. However, as I understand it, it

is not essential that this information be identifiable for quality assurance purposes. Would it be possible to separate the data items needed for quality assurance purposes only and submit those items in de-identified form?

5. How long will this information be maintained in a data base and is there a long-term objective for its maintenance? Once all objectives for the collection of this information have been achieved will it be destroyed?

6. And finally, it is my belief that many patients seek the services of home health agencies to preserve their independence and their sense of dignity. Patients often elect to stay home in order to maintain a sense of control and privacy. Wouldn't an assessment which is conducted every 60 days, funneling personally identifiable information into a national data base, deny patients the privacy they have come to expect?

It is my hope that with the impending implementation of OASIS on April 26, 1999, HCFA will make privacy a top priority as the final revisions to this program are made.

I thank you for your consideration and look forward to your response and to working with you to resolve this urgent and important issue within the next few weeks.

Sincerely,

Edward J. Markey