Advance Directives (Medicare and Medicaid) and Supporting Regulations CMS-R-10

A. BACKGROUND

This information collection package is a request for a reinstatement of the information collection requirements previously approved under CMS-R-10 (0938-0610). We have made revisions to our estimates of the number of adult Americans that would require documentation related to the presence of an Advance Directive and the number of providers and organizations that are subject to the Advance Directives requirements. These revisions consequently affect the number of hours required and the amount of money expended on this requirement.

The current information collection requirement for CMS-R-10 are 42 CFR 489.102, 417.436(d), 417.801, 422.128, 430.12(c)(1)(ii), 431.20, 431.107, 438.6, 440.170, 483.10, 484.10(c)(1)(ii), 485.601 and 489.102.

The Advance Directives requirement was enacted because Congress wanted individuals to know that they have a right to make health care decisions and to refuse treatment even when they are unable to communicate. Steps were taken at both the Federal and State level, to afford greater opportunity for the individual to participate in decisions made concerning the medical treatment to be received by an adult patient in the event that the patient is unable to communicate to others, a preference about medical treatment. The individual may make his preference known through the use of an Advance Directive, which is a written instruction prepared in advance, such as a living will or a durable power of attorney. This information is required to be documented in a prominent part of the individual's medical record, as specified at CFR 42 Section 489.102(a)(2). Advance Directives as described in the Patient Self-Determination Act (enacted in 1991) have increased the individual's control over decisions concerning medical treatment.

Prior to the enactment of the Omnibus Reconciliation Act of 1990 (OBRA '90), P.L. 101-508, there were no requirements relating to Advance Directives under Federal Medicare or Medicaid laws. Sections 4206 of OBRA '90 defined an Advance Directive as a written instruction recognized under State law relating to the provision of health care when an individual is incapacitated (those persons unable to communicate their wishes regarding Medical treatment).

When an Advance Directive exists for a patient, health care providers and organizations are required to follow through on the individual's preference, to the extent that State law permits/requires.

All states have enacted legislation defining a patient's right to make decisions regarding medical care, including the right to accept or refuse medical or surgical treatment and the right to formulate Advance Directives. Participating hospitals, skilled nursing facilities/nursing facilities, home health agencies, providers of home health care,

hospices, religious nonmedical health care institutions, and prepaid or eligible organizations (including Health Care Prepayment Plans (HCPPs) and Medicare Advantage Organizations (MAOs) such as Coordinated Care Plans, Demonstration Projects, Chronic Care Demonstration Projects, Program of All Inclusive Care for the Elderly, Private Fee for Service, and Medical Savings Accounts must provide written information, at explicit time frames, to all adult individuals about: a) the right to accept or refuse medical or surgical treatments; b) the right to formulate an Advance Directive; c) a description of applicable State law (provided by the State); and d) the provider's, or organization's policies and procedures for implementing an Advance Directive. Such information must include a statement of limitation if the provider cannot implement an Advance Directive as a matter of conscience. Also included is a provision to provide for the education of staff and community on issues concerning Advance Directives. Finally, providers and organizations must document in a prominent part of the individual's medical record whether or not the individual has executed an Advance Directive.

In accordance with CFR 42 Sections 489.102 and 422.128, States are required to provide to Medicaid providers, Cost Plans, HCPPs, and MAOs, as soon as possible but no later than 60 days, with revised copies of their description of State laws when revisions to those laws are enacted. Within that same time frame, States are required to amend their State plans. In turn, providers and organizations must revise and disseminate the amended information no later than 90 days from the effective date of a change in State law. Neither the statute nor regulation requires providers or organizations to distribute standard Advance Directive forms, nor to collect and maintain copies of executed Advance Directives. However, these practices are optional.

MAOs, Cost Plans, and HCPPs are permitted to contract with other entities to furnish information concerning Advance Directives requirements, but are legally responsible for ensuring Advance Directives statutory requirements are met. These organizations are also not relieved of their obligation to provide this information to the enrollee once he or she is no longer incapacitated or unable to receive such information. Follow-up procedures must be in place to ensure information is given directly to the individual at the appropriate time.

B. JUSTIFICATION

1. Need and Legal Basis

This action is authorized by sections 4206(a) and 4751 of OBRA '90 which amended several sections of the Social Security Act (the Act) and subjects certain Medicare and Medicaid providers and prepaid or eligible organizations to the requirement of maintaining written policies and procedures respecting Advance Directives.

The initial regulation on Advance Directives, an Interim Final Rule, was published on March 6, 1992. The Final Rule, published on June 27, 1995, confirmed the interim final

rule, with several minor changes based on CMS's review and consideration of public comments. The final rule clarified several statutory requirements; added a description of the minimum information that should be contained in a statement of limitation if an Advance Directive cannot be implemented because of an objection on the basis of conscience; provided a new requirement that providers and Health Maintenance Organizations (HMOs) must inform individuals that complaints concerning non-compliance with the Advance Directive requirements may be filed with the State survey and certification agency; specified that a patient has the right to use the home health hotline to lodge complaints concerning implementation of Advance Directive requirements; specified that an HHA may furnish Advance Directive information to a patient at the time of the first home visit, as long as the information is furnished before care is provided; specified that providers of personal care services may furnish Advance Directives information to a patient at the time of the first home visit, as long as the information is furnished before care is provided; and specified that personal care providers are permitted to contract with another entity to furnish Advance Directives information but are still legally responsible for ensuring that the Advance Directives requirements are met.

Section 4641 of the BBA of 1997, subsequently amended section 1866(f)(1)(B) of the Social Security Act to require that the patient's Advance Directives be placed in a prominent part of his/her medical record.

Section 4001 of the BBA of 1997 established a new Part C of the Medicare program, the Medicare+Choice (M+C) Program, 42 CFR Part 422. The term Medicare+Choice Program was changed to Medicare Advantage (MA) Program, by the Medicare Modernization Act on December 8, 2003. Note also that the terms health maintenance organization (HMOs) and Managed care organizations (MCOs) have been replaced by the terminology Medicare Advantage Organizations (MAOs). Many of the MAOs, and Health Care Prepayment Plans (HCPPs) previously covered under part 417 are now covered under part 422 because Section 4002 of the BBA of 1997 specifies that the requirements of section 1866(f) of the Act, which apply to section 1876 contractors, also applies to MAOs. MAOs are permitted to contract with other entities to furnish information concerning Advance Directives requirements. MAOs are legally responsible for ensuring that the Advance Directives statutory requirements are met.

Organizations which continue to have contracts under Part 417 (e.g., Cost Plans, HCPPs, and MAOs) continue to be subject to the Advance Directives requirements in Part 417.

The MA (previously M+C) regulation package implementing the BBA provisions concerning MA and Advance Directive requirements was published in the Federal Register on June 26, 1998. Subpart §422.128 of this regulation requires that each MAOs maintain written policies and procedures that meet the requirements for Advance Directives, as set forth in subpart I of part 489. The MA program is not relieved of its obligation to provide this information to the enrollee once he or she is no longer incapacitated or unable to receive such information. Follow-up procedures must be in place to ensure that the information is given directly to the individual at the appropriate

time.

Sections 1102 and 1871 of the Social Security Act revised 489.102(a) in 1999 to include Religious Nonmedical Health Care Institutions (§440.170) to the list of institutions that must maintain written policies and procedures concerning Advance Directives. This revision also requires that 489.102(a) include the requirement to document in a prominent part of the individual's current medical record or patient care record, in the case of an individual in a religious nonmedical health care institution, whether or not the individual has executed an Advance Directive. (It is not required to maintain a copy of the Advance Directive in the medical/patient care record).

States are required to provide to Medicaid providers, MAOs, and MCOs, as soon as possible but no later than 60 days, revised copies of their description of State laws when revisions to those laws are enacted. Within that same time frame, States are required to amend their State plans. In turn, providers and organizations must revise and disseminate the amended information no later than 90 days from the effective date of a change in State law. Neither the statute nor regulation requires providers or organizations to distribute standard Advance Directive forms, nor to collect and maintain copies of executed Advance Directives. This is, however, an option that many may take.

The CFRs on Advance Directives set forth statutory requirements for providers or organizations as follows:

42 CFR Part §417--Health Maintenance Organizations, Competitive Medical Plans, and Health Care Prepayment Plans

§417.436--Rules for Enrollees

- §417.436(d)--Advance Directives - Cross-references Subpart I - Advance Directives §489.102--Requirements for Providers

- §417.801--Advance Directives - Cross-references §489.100 and §417.436(d)--Advance Directives

42 CFR Part §422--Medicare Advantage Program

- §422.128--Advance Directives - Cross-references §489.100. Extends the full coverage of §489 to include MAOs.

- As defined in §422 and in accordance with the BBA of 1997, no CMPs (Section 1876 contracts) can be renewed for a contract year beginning on or after December 31, 2002. Instead, both CMPs and MCOs will exist under MAOs.

42 CFR Part §430--Grants to States for Medical Assistance Programs

- **§**430.12(c)(1)(ii)--Submittal of State plans and plan amendments -- The State plan must provide that it will be amended whenever necessary to reflect any changes related to Advance Directives. Such amendments must be submitted as soon as possible, but not later than 60 days from the effective date of the change to State law.

42 CFR Part §431--State Organization and General Administration

- **§**431.20--Advance Directives. Prescribes State plan requirements for the development and distribution of a written description of State law concerning Advance Directives.

- **§**431.107--Required Provider Agreement. State plan must provide for an agreement between the Medicaid agency and each provider or organization providing services under the plan in which the provider or organization agrees to comply with the Advance Directives for hospitals, nursing facilities, providers of home health care and personal care services, hospices, and MCOs specified in part 489, subpart 1, and**§**417.436(d). Those organizations that contract with CMS only under the MA program are covered under part **§**422 and are also included under **§**431.107.

42 CFR §Part 438--Contracts (In Lieu of 434.28 which is obsolete)

- **§**438.6--Contract Requirements - Cross references Part 489, Subpart I.

42 CFR §Part 440.170 – Religious Nonmedical Health Care Institutions

- §440.170--Medicaid Provisions – Part 489, Subpart I - Advance Directives. Revised §489.102(a)(2) to reflect that an individual's Advance Directive be placed in a "prominent part" of his or her medical record.

42 CFR §Part 483--Requirements for States and Long Term Care

- **§**483.10--Resident rights. - Cross references Part 489, Subpart I

42 CFR §Part 484--Conditions of Participation: Home Health Agencies
Subpart B--Administration

- **§**484.10(c)(1)(ii)--Condition of Participation: Patient rights/Right to be informed and to participate in planning care and treatment. - Cross-references to Part 489, Subpart I.

42 CFR §485-- Critical Access Hospitals – Cross references Part 489, Subpart I

- **§**485--Conditions of Participation (CoPs) do not explicitly address

Advance Directives. CoPs will be revised in the future to specifically address this requirement.

42 CFR §Part 489--Provider Agreements and Supplier Approval

- §489.102--Requirements for Providers. With the 1999 edition of 42 CFR, all text of §489 will be republished without revision, with the exception of paragraph §489.102(a)(2), which will be revised to reflect that each provider must document in a prominent part of the individual's medical record whether or not the individual has executed an Advance Directive.

Though 42 CFR §489.102 does not explicitly specify the point in time when the documentation is to be made in the individual's medical records, it does delineate specific time frames for the required information to be disseminated to the patient. Documentation should continue to be made at these times, unless otherwise indicated by regulation. The statutory time frames for dissemination of information are as follows:

(a) In the case of a hospital, at the time of the individual's admission as an inpatient.

(b) In the case of a skilled nursing facility/nursing facility, at the time of the Individual's admission as a resident.

(c) In the case of a home health agency, or provider of home health care or personal care services, in advance of the individual coming under the care of the agency or provider.

(d) In the case of a hospice program, at the time of initial receipt of hospice care by the individual from the program.

(e) In the case of an eligible organization (as addressed in §1876(b) and §1833(a)(1)(A), or §1903(m)(1)(A), e.g., MCO or MA organization), at the time of enrollment of the individual with the organization.

2. Information Users

The advanced directives documentation is used only by medical or other personnel employed by the provider or organization, on an as needed basis.

3. Use of Information Technology

The information requirement in this regulation merely specifies documentation in a prominent part of the medical record and does not prescribe format of collection or maintenance procedures. Since the information is collected during the course of a personal interview of the patient by personnel from a provider or organization, more automated or technological methods of collection are not appropriate.

4. Duplication

   There is no duplication associated with this regulatory requirement.

5. Small Business Impact

   The requirements do affect small businesses; however, the general nature of the requirements allows flexibility for facilities to meet the requirements in a way that is consistent with their existing operations.

6. Less Frequent Collection

   This information is collected only when patients are asked about advanced directives. The collection is mandated by law and regulation. If it were to be collected less frequently, CMS would be unable to obtain this data.

7. Special Circumstances Leading to Information Collection

   There are no special circumstances for collecting this information.

8. Federal Register Notice/ Outside Consultation

   The 60-day Federal Register notice published July 26, 2013.

9. Payment or Gift to Respondent

   No payments or gifts are made to respondents.

10. Confidentiality

    Since this activity involves documenting the medical record, these requirements are subject to the confidentiality requirements of the Health Insurance Portability and Accountability Act of 1996, which includes privacy requirements for medical records.

11. Sensitive Questions

    Although subject matter is of a sensitive nature to many, it does not fall into any of the categories listed in the CMS Administrative Issuance Guidelines for OMB review.

12. Burden Estimate (Hours and Wages)

    We estimate a total of **39,575** providers and organizations will be affected by this information collection. The following list indicates the approximate number of providers and organizations by subject and by regulation, cited for easy reference.

Advance Directive Requirement	Providers/Suppliers/Organizations	Current Number	Number of New
§489.102(a)(2)	Hospitals (Includes 18 RNHCIs) Critical Access Hospitals Hospices SNF/NFs HHAs	**6,168** **1,329** **3,795** **15,151** **12,452**	**0** **270** **410** **87** **1,449**
§417.436(d)(iii)	Cost Plans HCPPs	**18** **10**	**0** **0**
§422.128	Medicare Advantage Organizations (MAOs) & PACE	**652**	**60**
Total # of organizations		**39,575**	**2,276**

A. One-Time Start-Up Costs

We estimate a one-time burden of 2,276 hours will be required to develop a standard Advance Directive for new providers and organizations. This is based on 1 hour per provider and organization (2,276 x 1 hour = 2,276).

We estimate a one-time burden of 4,552 hours will be required to develop policies and procedures to implement the Advance Directives requirement. This is based on 2 hours per provider and organization (2,276 x 2 hours = 4552).

B. Annual Costs

We estimate 2,770,250 hours will be required to document this information in FY '13. We anticipate that 55 million individuals will receive services annually from a total of 39,575 organizations. The number of providers and organizations was retrieved from the CMS CASPER Data System as of May 2013. The number of Cost Plans, HCPPs, Medicare Advantage Organization and Programs for All-Inclusive Care for the Elderly (PACE) was retrieved from the CMS Monthly Contract and Enrollment Summary Report. The number of patients who will receive services each year is based on yearly adult enrollments in Medicare and Medicaid over the last 3 years. We are using this number as a proxy for the number of patients receiving services from affected providers and organizations because we do not have an accurate number of all patients receiving services from all affected providers and organizations.

> We estimate that it takes 3 minutes for medical or other personnel of providers and organizations to document an individual's Advance Directive preference(s) in the medical record. Our calculations are: 55 million patients nationwide / 39,575 providers and organizations nationwide = 1,390 patients per provider or organization.

1,390 patients per provider or organization x 3 minutes per patient = 4,170 minutes per provider or organization / 60 = 70 hours per provider or organization.

70 hours per provider or organization x 39,575 providers and organizations nationwide = 2,770,250 hours nationwide.

We estimate that it takes 2 hours annually for providers and organizations to revise policies and procedures and to train staff, patients, and community on the Advance Directives requirement.

Cost Estimates to Respondent or Record keeper

(a) We estimate the one-time cost associated with developing the appropriate policies and procedures to implement the Advance Directives requirement to be $154,768. We expect that a nurse would develop the policies and procedures based on recommendations from the Director. (The Bureau of Labor Statistics for 2012 specifies that the hourly salary of a nurse is $34). We estimate that complying with this specific requirement will take 2 hours.

(b) There is a one-time cost associated with developing an Advance Directive. We estimate that a typical Advance Directive message might be in three parts: An introduction; the information section; and a section for follow-up questions and issues. We expect that a nurse would initially develop the Advance Directive resource. We estimate the effort to develop this one-time message would not exceed one hour at a cost of $34 for each provider or organization. We estimate that there will be 2,276 new providers and organizations entering the Medicare program over the next 3 years. We estimate the total one time cost associated with developing the Advance Directive to be $77,384.

(c) All providers and organizations subject to this Advance Directive requirement must develop and implement policies and procedures that ensure documentation, in a prominent part of the individual's medical record that specifies whether or not the individual has executed an Advance Directive. We estimate $47,094,250 as the annualized costs for all respondents to document medical records with this information. Our estimation that it takes approximately 3 minutes for a provider's or organization's staff to complete this documentation is unchanged. We estimate that documenting the patient's record will likely be performed by a Billing and Posting Clerk. Based on Bureau of Labor Statistics for 2012, the hourly salary of a Billing and Posting Clerk is $17 an hour.

(d) We have also developed an estimate of the annual cost of 1 ½ hours, which we estimate to be required to maintain policies and procedures and to update staff, patients and the community annually for Advance Directives. We estimate $2,018,342 as the annualized costs for respondents to train and update policies and procedures for Advance

Directives.

Activity	Responsible Staff	Hrly Wage	# of Prvdrs & Orgs	# of Hrs per Prvdr & Org.	Total # of Hrs for all Prvdrs & Orgs	Total Costs
(a) Develop Policies & Procedures	Nurse	$34	2,276	2	4,552	$154,768
(b) Develop Advance Directive	Nurse	$34	2,276	1	2,276	$77,384
(c) Document Record with Advance Directives Information	Billing and Posting Clerk	$17	39,575	70	2,770,250	$47,094,250
(d) Yearly training & update of policies and procedures	Nurse	$34	39,575	1.5	59,363	$2,018,342
TOTAL			2,276-39,575		2,836,441	49,344,744

13. Capital Costs

There are no capital costs.

14. Cost to Federal Government

We estimate no Federal costs associated with this information collection requirement.

15. Changes to Burden

Changes to the burden estimates have changed due to the increase in the number of individuals who will receive services annually. Additionally, the total of organizations increased as a whole but there is a decrease in the amount of providers that will now be affected by the 1one-time burden. There was an increase to the wages of the Billing and Posting Clerk.

16. Publication and Tabulation Dates

There are no publication and tabulation dates.

17. Expiration Date

This collection does not lend itself to the displaying of an expiration date. It is revised every three years.