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

A. BACKGROUND

This information collection package is a request for extension of the information collection requirements previously approved under CMS-R-10 (0938-0610). We have modified 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 modifications 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), and 485.60.

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. Now, under broad federal requirements enacted through OBRA, each state has its own laws, requirements and procedures with regard to Advanced Directives. CMS ensures only that federal requirements are met.

Section 4206 of OBRA 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.

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.

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

   Federal law mandates that information be collected when patients are asked about advanced directives; however CMS does not collect this data, it only requires that it be collected. Each state has its own laws, requirements and procedures with regard to Advanced Directives information collection. CMS ensures only that federal requirement for information collection is met

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 December 9, 2016 (81 FR 89104). There were a few comments received and they have been addressed.

   The 30-day Federal Register notice published February 17, 2017 (82 FR 11037). There were no public comments

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 **39,479** 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/ NFHHA	**6,142** **1,334** **3,466** **15,637** **12,268**	**-26** **5** **-329** **486** **-184**
§417.436(d)(iii)	Cost Plans HCPPs	**16** **9**	**-2** **-1**
§422.128	Medicare Advantage Organizations (MAOs) & PACE	**607**	**-45**
Total # of organizations		**39,479**	**-96**

A. One-Time Start-Up Costs

We estimate a one-time burden of 0 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 (0 x 1 hour = 0).

We estimate a one-time burden of 0 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 (0 x 2 hours = 0).

B. Annual Costs

We estimate 2,763,530 hours will be required to document this information in FY ’16. We anticipate that 55 million individuals will receive services annually from a total of 39,479 organizations. The number of providers and organizations was retrieved from the 2015 CMS Statistics Reference Book. 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 / 39,479 providers and organizations nationwide = 1,393 patients per provider or organization.

> 1,393 patients per provider or organization x 3 minutes per patient = 4,179 minutes per provider or organization / 60 = 70 hours per provider or organization.
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> 70 hours per provider or organization x 39,479 providers and organizations nationwide = 2,763,530 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 $0. We expect that a nurse would develop the policies and procedures based on recommendations from the Director. (The Bureau of Labor Statistics for 2015 specifies that the hourly salary of a nurse is $64). 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 $68 for each provider or organization. We estimate that there will be 0 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 $0.

(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 $93,960,020 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 2015, the hourly salary of a Billing and Posting Clerk is $34 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 $3,908,454 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	Total Costs
(a) Develop Policies &	Nurse	$68	0	2	0	$0
(b) Develop Advance Directive	Nurse	$68	0	1	0	$0
(c) Document Record with Advance Directives Information	Billing and Posting Clerk	$34	39,479	70	2,763,530	$93,960,020
(d) Yearly training & update of policies and procedures	Nurse	$68	39,479	1.5	59,219	$3,908,454
TOTAL			0 39,479		2,822,749	$97,868,474

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: (1) the decrease in the

number of participating providers and organizations as a whole from 39,575 to 39,479, and (2) the hourly wage for Nurse and Billing Clerk doubled due to adding 100% for overhead and fringe benefits, almost doubling the annual cost burden. The burden hours decreased from 2,836,441 to 2,822,749, but due to the doubling of the hourly wage for Nurse and Billing clerk, the total cost increased from $49,344,744 to $97,868,474.

16. Publication and Tabulation Dates

There are no publication and tabulation dates.

17. Expiration Date

CMS will publish a notice in the Federal Register to inform the public of both the approval and the expiration date. In addition, the public will be able to access the expiration date on OMB's website by performing a search using the OMB control number.