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§ 26.1701 To what does this subpart apply?

(a) For decisions under FIFRA (7 U.S.C. 136–136y) or section 408 of FFDCA (21 U.S.C. 346a), this subpart applies to research involving intentional exposure of human subjects to any substance.

(b) For decisions under any regulatory statute administered by EPA other than those statutes designated in paragraph (a) of this section, this subpart applies to research involving intentional exposure of human subjects to a pesticide.

§ 26.1702 Definitions.

The definitions in § 26.1102 and § 26.1202 apply to this subpart as well.

§ 26.1703 Prohibitions applying to all research subject to this subpart.

(a) Prohibition of reliance on scientifically invalid research. EPA must not rely on data from research subject to this subpart unless EPA determines that the data are relevant to a scientific or policy question important for EPA decisionmaking, that the data were derived in a manner that makes them scientifically valid and reliable, and that it is appropriate to use the data for the purpose proposed by EPA. In making such determinations, EPA must consider:

(1) Whether the research was designed and conducted in accordance with appropriate scientific standards and practices prevailing at the time the research was conducted.

(2) The extent to which the research subjects are representative of the populations for the endpoint or endpoints in question.

(3) The statistical power of the data to support the scientific conclusion EPA intends to draw from the data.

(4) In a study that reports only a No Observed Effect Level (NOEL) or a No Observed Adverse Effect Level (NOAEL), whether a dose level in the study gave rise to a biological effect, thereby demonstrating that the study had adequate sensitivity to detect an effect of interest.

(b) Prohibition of reliance on research subject to this subpart involving intentional exposure of human subjects who are pregnant women (and therefore their fetuses), nursing women, or children. Except as provided in § 26.1706, EPA must not rely on data from any research subject to this subpart involving intentional exposure of any human subject who is a pregnant woman (and therefore her fetus), a nursing woman, or a child.

§ 26.1704 Prohibition of reliance on unethical human research with non-pregnant, non-nursing adults which is not subject to § 26.1705.

(a) This section applies to research subject to this subpart that is not subject to § 26.1705.

(b) Except as provided in § 26.1706, EPA must not rely on data from any research subject to this section if there is clear and convincing evidence that:

(1) The conduct of the research was fundamentally unethical (*e.g.,* the research was intended to seriously harm participants or failed to obtain informed consent); or

(2) The conduct of the research was deficient relative to the ethical standards prevailing at the time the research was conducted in a way that placed participants at increased risk of harm (based on knowledge available at the time the study was conducted) or impaired their informed consent.

(c) The prohibition in this section is in addition to the prohibitions in § 26.1703.

§ 26.1705 Prohibition of reliance on unethical human research with non-pregnant, non-nursing adults initiated after April 7, 2006, and subject to subparts A through L of this part, or the codification of the Common Rule by another Federal department or agency.

(a) This section applies to research subject to this subpart, that:

(1) Was initiated after April 7, 2006.

(2) Was subject, at the time it was conducted, either to subparts A through L of this part, or to the codification of the Common Rule by another Federal department or agency.

(b) Except as provided in § 26.1706, EPA must not rely on data from any research subject to this section unless EPA determines that the research was conducted in substantial compliance with either:

(1) All applicable provisions of subparts A through L of this part, or the codification of the Common Rule by another Federal department or agency; or

(2) If the research was conducted outside the United States, with procedures at least as protective of subjects as those in subparts A through L of this part, or the codification of the Common Rule by another Federal department or agency.

(c) Except as provided in § 26.1706, EPA must not rely on data from any research subject to this section unless EPA determines that the research was conducted in substantial compliance with either:

(1) A proposal that was found to be acceptable under § 26.1603(c), and no amendments to or deviations from that proposal placed participants at increased risk of harm (based on knowledge available at the time the study was conducted) or impaired their informed consent. If EPA discovers that the submitter of the proposal materially misrepresented or knowingly omitted information that would have altered the outcome of EPA's evaluation of the proposal under § 26.1603(c), EPA must not rely on that data.

(2) A proposal that would have been found to be acceptable under § 26.1603(c), if it had been subject to review under that section, and no amendments to or deviations from that proposal placed participants at increased risk of harm (based on knowledge available at the time the study was conducted) or impaired their informed consent.

(d) The prohibition in this section is in addition to the prohibitions in § 26.1703.

§ 26.1706 [Amended]

21. In paragraph (d) of § 26.1706 remove the word "publishes" and add in its place the phrase "has published".

[FR Doc. 2011–1629 Filed 2–1–11; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 416, 418, 482, 483, 484, 485, 486, and 491

[CMS–3225–P]

RIN 0938–AP94

Medicare and Medicaid Programs; Patient Notification of Right To Access State Survey Agencies and Medicare Beneficiary Notification of the Right To Access Quality Improvement Organizations

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Proposed rule.

SUMMARY: This proposed rule would set forth new requirements for Medicare certified providers and suppliers. This proposed rule would require that the Medicare certified providers and suppliers make available to their Medicare beneficiaries information about their right to file a written complaint with the Quality Improvement Organization (QIO) in the State where healthcare services are being or were provided about the quality of care they are receiving or have received. The Medicare certified providers and suppliers would be required to provide their Medicare beneficiaries with written notice of the QIO's contact information. In addition, we are proposing new requirements for certain Medicare providers and suppliers that would require facilities to inform all patients about State agency contact information.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on April 4, 2011.

ADDRESSES: In commenting, please refer to file code CMS–3225–P. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of four ways (please choose only one of the ways listed):

1. *Electronically.* You may submit electronic comments on this regulation to *http://www.regulations.gov.* Follow the instructions under the "More Search Options" tab.

2. *By regular mail.* You may mail written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–3225–P, P.O. Box 8010, Baltimore, MD 21244–8010.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–3225–P, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

4. *By hand or courier.* If you prefer, you may deliver (by hand or courier) your written comments before the close of the comment period to either of the following addresses:

a. For delivery in Washington, DC—Centers for Medicare & Medicaid Services, Department of Health and Human Services, Room 445–G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201.

(Because access to the interior of the Hubert H. Humphrey Building is not readily available to persons without Federal government identification, commenters are encouraged to leave their comments in the CMS drop slots located in the main lobby of the building. A stamp-in clock is available for persons wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed.)

b. For delivery in Baltimore, MD—Centers for Medicare & Medicaid Services, Department of Health and Human Services, 7500 Security Boulevard, Baltimore, MD 21244–1850.

If you intend to deliver your comments to the Baltimore address, please call telephone number (410) 786–9994 in advance to schedule your arrival with one of our staff members.

Comments mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and received after the comment period.

Submission of comments on paperwork requirements. You may submit comments on this document's paperwork requirements by following the instructions at the end of the "Collection of Information Requirements" section in this document.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT: Jacqueline Morgan, (410) 786–4282.

SUPPLEMENTARY INFORMATION: *Inspection of Public Comments:* All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following Web site as soon as possible after they have been received: *http://www.regulations.gov.* Follow the search instructions on that Web site to view public comments.

Comments received timely will also be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244, Monday through Friday of each week from 8:30 a.m. to 4 p.m. To schedule an appointment to view public comments, phone 1–800–743–3951.

I. Legislative and Regulatory Background

Various sections of the Social Security Act (the Act) define the terms used for each Medicare provider and supplier. In some cases, those definitions describe requirements that Medicare certified providers and suppliers must meet for purposes of the Medicare program. Some of those provisions also specify that the Secretary of the Department of Health and Human Services (DHHS) (the Secretary) may establish other requirements as necessary in the interest of health and safety of patients. The Public Health Service (PHS) Act also specifies additional requirements that some Medicare certified providers and suppliers must meet.

The Secretary has established in regulation the requirements that each provider and supplier must meet in order to participate in the Medicare and Medicaid programs. These requirements are called the Conditions of Participation (CoPs), or Requirements (for Long Term Care Facilities) for providers and the Conditions for Coverage (CfCs) for suppliers. The CoPs and CfCs establish health and safety measures that are intended to ensure that a minimum level of quality care is furnished to all Medicare patients.

To assist with improving the quality of health care for Medicare patients, we propose to establish a new standard for the following 10 Medicare certified providers and suppliers:

- Ambulatory Surgical Centers (ASCs).
- Hospices.
- Hospitals.
- Long Term Care (LTC) Facilities.
- Home Health Agencies (HHAs).
- Comprehensive Outpatient Rehabilitation Facilities (CORFs).
- Critical Access Hospitals (CAHs).
- Clinics and Rehabilitation Agencies.
- Portable X-Ray Services.
- Rural Health Clinics (RHCs) and Federally Qualified Health Centers (FQHCs).

II. Quality Improvement Organizations

Section 142 of the Peer Review Improvement Act of 1982 (Title I, Subtitle C of the Tax Equity and Fiscal Responsibility Act (TEFRA) of 1982 (Pub. L. 97–248)) amended section 1862 of the Act by adding new subsection (g), which requires that the Secretary enter into contracts with utilization and quality control peer review organizations (PROs). These organizations make determinations about whether care is reasonable and medically necessary, or is custodial in

nature. They also promote the effective, efficient, and economical delivery of care, and promote the quality of that care. In 2002, CMS began referring to these Peer Review Organizations as Quality Improvement Organizations (QIOs). (*See* 67 FR 36539.) The national Quality Improvement Organization (QIO) Program was established to improve the efficiency, effectiveness, economy and quality of services delivered to Medicare beneficiaries. CMS contracts with 53 QIOs (one in each State, Puerto Rico, the District of Columbia, and the U.S. Virgin Islands) for a term of 3 years.

Section 143 of TEFRA added sections 1151 through 1163 in Part B of Title XI of the Act, which established the Utilization and Quality Control Peer Review Program. Section 1151 of the Act sets out the purpose of Part B of title XI of the Act. Section 1152 of the Act defines the entities that can qualify as QIOs, including the requirement that the QIO must be composed of a substantial number of the "licensed doctors of medicine and osteopathy engaged in the practice of medicine or surgery" in the QIO's area of responsibility. Alternatively, the QIO must have available the services of a sufficient number of licensed doctors of medicine or osteopathy engaged in the practice of medicine or surgery in its area to assure adequate peer review of the services provided by the various medical specialties and subspecialties. Section 1153 of the Act provides specific requirements regarding how contracts between the QIOs and CMS must be structured. Section 1154(a)(1) of the Act describes the QIOs' responsibility to determine whether a provider's or practitioner's services and items are reasonable and medically necessary, provided in the appropriate setting, and whether the quality of services meets "professionally recognized standards" of care. QIOs also have the specific responsibility under section 1154(a)(14) of the Act to conduct an "appropriate review of all written complaints about the quality of services (for which payment may otherwise be made under title XVIII) not meeting professionally recognized standards of health care. * * *" A complaint can only be reviewed and resolved by the QIO if filed by an individual entitled to benefits for such services under Medicare (or a person acting on the individual's behalf). The QIO's review responsibility applies to any beneficiary's complaint, even if the issues raised do not appear to the QIO to involve serious or substantial quality violations.

As part of the effort to evaluate the QIO program, section 109(d)(1) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) mandated the Institute of Medicine (IOM) to conduct a review of the program and to recommend how its impact could be enhanced. IOM published the final report on March 9, 2006 and it can be found at *http://www.iom.edu/Reports/2006/Medicares-Quality-Improvement-Organization-Program-Maximizing-Potential.aspx.* One of the issues the report highlighted was that QIOs perform few beneficiary complaint reviews.

We believe that a factor contributing to the low volume of beneficiary complaint reviews is that beneficiaries are unaware of their right to voice complaints to the QIO in their State. CMS, in the past, has instituted efforts to inform beneficiaries of their right to report to their respective QIOs, concerns they have about the quality of care they receive. These efforts have included the incorporation of a specific provision in the Hospital CoPs at § 482.13(a)(2) that includes a requirement that the grievance process must include a mechanism for timely referral to the appropriate Utilization and Quality Control Quality Improvement Organization of beneficiary concerns regarding quality of care. In accordance with section 1866(a)(1)(M) of the Act, hospitals and critical access hospitals (CAHs) must deliver, at or about the time of patient admission, the "Important Message from Medicare" (IM) to all inpatient Medicare beneficiaries which explains their Medicare rights, including appeal rights. The IM informs beneficiaries of their right to report to the QIO any concerns about the quality of care they received. It also requires that the hospital provide the name of the QIO and the QIO's contact information. The current data shows that QIO utilization rates are higher among in-patient Medicare beneficiaries than among Medicare beneficiaries who receive care in other settings. Under the current QIO 9th Statement of Work (8/1/2008 through 7/31/11), the QIOs have received 6,379 inpatient and 4,116 outpatient requests for complaint reviews.

III. Provisions of the Proposed Rule

Over the past decade, quality of health care has been of increasing concern. CMS recognizes this concern and has started revising patient health and safety regulations to include quality assessment and performance improvement requirements.

Currently, Medicare beneficiaries receiving hospital in-patient services are informed of their right to communicate health care concerns to a QIO. We believe that this requirement should also be provided to Medicare out-patient beneficiaries and to those beneficiaries receiving care in other healthcare settings. To further assist in improving quality of health care, we are proposing to include a new standard for 10 specific Medicare certified providers and suppliers (that is, CoPs or CfCs). The new standard would inform Medicare beneficiaries of their right to communicate health care concerns to a QIO. These standards are applicable only to Medicare beneficiaries because QIOs are only authorized to review the health care quality complaints of Medicare beneficiaries.

As part of this effort, we propose that Medicare beneficiaries be informed by written notice at the start of care (or, for some providers or suppliers, at the time of inpatient admission or at an initial assessment visit in advance of furnishing care) of their right to voice concerns about the quality of care they are receiving (or, once services have been furnished, have received) to the QIO in the State where services are being or have been provided. We also propose that the facility document that it presented written notice to the beneficiary or the beneficiary's representative or a surrogate selected by the beneficiary, such as a family member or friend of the beneficiary. This person may act as a liaison between the beneficiary and the provider/supplier to help the beneficiary communicate, understand, remember and cope with the interactions that take place during their visit/stay, and explain any instructions to the beneficiary that are delivered by the provider or supplier. If a patient is unable to fully communicate directly with the provider or supplier, then the provider or supplier may give written information to the beneficiary's representative or surrogate. Patient representatives or surrogates are not intended to serve as interpreters for limited English proficient (LEP) or deaf/hard of hearing persons. Under regulations issued pursuant to Title VI of the Civil Rights Act of 1964 (Title VI), recipients of Federal funds such as health care providers must take reasonable steps to provide LEP persons with meaningful access to programs and activities. Further, under Section 504 of the Rehabilitation Act of 1973, recipients must ensure effective communication with persons with disabilities, including those who are deaf or hard of hearing. Under both laws, interpreters necessary for

meaningful access and effective communication are to be provided free of charge. If a patient wishes his or her representative or surrogate to serve in the capacity of interpreter, the provider or supplier can obtain a signed waiver from the patient documenting that a free interpreter was offered and declined in favor of using the representative or surrogate. In any case, the provider or supplier continues to be responsible for ensuring the language access and effective communication. Where necessary for compliance with Title VI, providers and suppliers should provide written translations for LEP persons, particularly for languages that are commonly used by non-English-speaking beneficiaries, such as Spanish.

These proposed requirements are based on the provisions that are already established for those Medicare beneficiaries receiving care in a hospital setting. At this time, we are not proposing to require that a specific format be utilized. Entities will have the flexibility to design their own notice and documentation process.

This proposed rule would affect the following Medicare certified providers and suppliers: (1) Ambulatory Surgical Centers (ASCs); (2) Hospices; (3) Hospitals; (4) Long Term Care Facilities (LTCs); (5) Home Health Agencies (HHAs); (6) Comprehensive Outpatient Rehabilitation Facilities (CORFs); (7) Critical Access Hospitals (CAHs); (8) Clinics and Rehabilitation Agencies; (9) Portable X-ray Services; and (10) Rural Health Clinics (RHCs) and Federally Qualified Health Centers (FQHCs).

In addition to informing Medicare beneficiaries about QIO contact information, we have also included a proposed requirement for seven out of the ten providers and suppliers that requires each of them to inform all patients, including Medicare beneficiaries, about State agency contact information. We wanted to be sure patients also had information about filing a complaint with the State survey agency. As we mentioned previously, CMS is continually updating the health and safety standards of various providers and suppliers and, as a result, Ambulatory Surgical Centers, Long Term Care Facilities, and Home Health Agencies already have existing regulations that require them to provide patients with State survey agency contact information. We propose to add the State agency contact information requirement to the following seven types of providers and suppliers: Hospices, Hospitals, CORFs, CAHs, Clinics and Rehabilitation Agencies, Portable X-ray Services and RHCs and FQHCs.

Medicare health and safety standards are in place to protect patients. All patients receiving care at Medicare-certified facilities have the right to file a complaint or grievance with the State agency against a Medicare provider or supplier for improper care or treatment. The State survey agency and CMS work together to make sure providers and suppliers meet Federal standards. Medicare beneficiaries can file a complaint with the State agency and/or a QIO. It is our intent to ensure that, as part of patient rights, patients receive complete information about filing a complaint in the event they have a healthcare concern or complaint about the care they received from a Medicare certified facility. In the event that a QIO received a complaint from a non-Medicare beneficiary, we expect that the QIO would explain that complaints are covered only for Medicare beneficiaries and the individual should contact the facility directly for procedures for filing a complaint and information on contacting the appropriate State survey agency.

Some Medicare certified providers and suppliers were determined not to be appropriate for inclusion in this proposed rule for various reasons. For example, End Stage Renal Disease (ESRD) facilities are excluded from this proposed requirement because they already have a specific complaint process built into the ESRD Network System that is similar to the QIO complaint process. At this time, we would also like to solicit comments on whether this QIO notice should also be given at the end of a Medicare beneficiary's treatment, service or hospitalization. Another option may be to only require that the QIO notice be given upon completion of treatment or discharge (in addition to the notification upon admission) if the Medicare beneficiary has experienced an adverse event.

CMS Data Resource

The data regarding the number of Medicare certified providers and suppliers that would be affected by this proposed rule would be generated by CMS' Online Survey, Certification, and Reporting (OSCAR) data system as of December 31, 2008. We note that the OSCAR system is updated frequently by individual States. Thus, the figures may not always total 100 percent.

A. Ambulatory Surgical Centers (§ 416.50)

Section 42 CFR 416.2 defines an ambulatory surgical center (ASC) as any distinct entity that operates exclusively for the purpose of providing surgical services to patients not requiring hospitalization, in which the expected duration of services would not exceed 24 hours following an admission.

The surgical services performed at ASCs are scheduled, primarily elective, non-life-threatening procedures that can be safely performed in an ambulatory setting. Patients are examined immediately before surgery to evaluate the risk of anesthesia and of the procedure to be performed. Patients are also evaluated before discharge from the ASC to ensure that there has been proper anesthesia recovery. Currently, there are 5,174 Medicare certified ASCs in the United States. Most ASCs are small physician-owned entities.

The ASC CfCs are located at § 416.40 through § 416.52. Currently, the patient rights standard for ASCs specifies that the ASC must inform the patient or the patient's representative of the patient's rights, and must protect and promote the exercise of such rights. In addition, it states that the ASC must provide the patient or the patient's representative with verbal and written notice of the patient's rights in advance of the date of the procedure, in a language and manner that the patient or the patient's representative understands. To further assist with improving the quality of health care, we are proposing to revise the ASC patient rights requirement at § 416.50 by redesignating paragraph (c) as paragraph (d) and paragraph (d) as paragraph (e) and adding a new standard at paragraph (c). The proposed standard would require the ASC to inform all Medicare beneficiaries by written notice, at the time of admission, of their right to file a written complaint with the QIO in the State where services are being or were provided about the quality of care they are receiving or have received. In addition, the new standard would require that the ASC provide Medicare beneficiaries with the name, telephone number, electronic mail address, and mailing address of the QIO, as well as require that the ASC document in the beneficiary's record that it has presented the written notice to the beneficiary or beneficiary's representative or surrogate.

B. Hospice Care (§ 418.52)

Section 122 of TEFRA, Public Law 97–248, added section 1861(dd) to the Act to provide coverage for hospice care to terminally ill Medicare beneficiaries who elect to receive care from a Medicare-participating hospice. Under section 1861(dd) of the Act, the Secretary has established the CoPs that a hospice must meet in order to participate in the Medicare and Medicaid programs or both programs.

Under section 1861(dd) of the Act, the Secretary is responsible for ensuring that the CoPs and their enforcement are adequate to protect the health and safety of individuals under hospice care. The hospice care CoPs at § 418.52 through § 418.116 apply to a hospice as an entity, as well as to the services furnished to each individual under hospice care.

Hospice care provides palliative care rather than traditional medical care and curative treatment to terminally ill individuals. Palliative care improves the quality of life of patients and their families facing the problems associated with life-threatening illness through the prevention and relief of suffering by means of early identification, assessment, and treatment of pain and other issues. Hospice care allows the patient to remain at home as long as possible by providing support to the patient and family, and by keeping the patient as comfortable as possible while maintaining his or her dignity and quality of life. A hospice uses an interdisciplinary approach to deliver medical, social, physical, emotional, and spiritual services through the use of a broad spectrum of caregivers. Currently, there are 3,346 hospice agencies nationally.

The patient's rights standard for hospice care currently states that the patient has the right to be informed of his or her rights, and that the hospice must protect and promote the exercise of these rights. However, it does not state that the patient is to receive State survey agency information to report complaints or to be informed of his or her right to communicate health care quality concerns to a QIO. Therefore, we are proposing to include these requirements by revising the hospice patient's rights requirements at § 418.52 by adding a new requirement at proposed paragraph (c)(9). We are also proposing to add a new standard at proposed paragraph (d). At proposed paragraph (c)(9), we are proposing that the hospice provide patients with the mailing address, electronic mail address, and telephone number of the State survey agency in the event they wish to report a grievance. The proposed new standard at paragraph (d) would require the hospice to inform all Medicare beneficiaries by written notice, during the initial assessment visit in advance of furnishing care, of their right to file a written complaint about the quality of care they are receiving or have received to the QIO in the State where services are being provided or were provided. In addition, the proposed standard would require the hospice to provide Medicare beneficiaries with the name, telephone number, electronic mail address, and mailing address of the QIO, as well as require that the hospice document in the beneficiary's records that it presented the written notice to the beneficiary or beneficiary's representative or surrogate.

C. Hospitals (§ 482.13)

Section 1861(e)(1) through (8) of the Social Security Act (the Act) defines the term "hospital" and lists the requirements that a hospital must meet to be eligible for Medicare participation. Section 1861(e)(9) of the Act specifies that a hospital must also meet such other requirements as the Secretary finds necessary in the interest of the health and safety of the hospital's patients. Under the authority of 1861(e), the Secretary has established in regulations at 42 CFR part 482 the requirements that a hospital must meet to participate in the Medicare program.

Section 1905(a) of the Act provides that Medicaid payments may be applied to hospital services. Regulations at § 440.10(a)(3)(iii) require hospitals to meet the Medicare conditions of participation (CoPs) to qualify for participation in Medicaid. The hospital CoPs are found at § 482.1 through § 482.66.

We are proposing to amend the patient's rights requirements at § 482.13 by adding a new requirement at subparagraph (a)(1)(i). To remain consistent among providers and suppliers, we are proposing to require that hospitals provide patients with the address and telephone number of the State survey agency to report complaints. Currently, our patient's rights regulation at § 482.13(a)(2) already requires hospitals to provide all patients with a grievance process. This regulation also includes the timely referral, for Medicare beneficiaries, to a QIO about complaints regarding the quality of care and discharges, similar to the proposals we are making here for other providers and suppliers. We are also proposing to add new standards at § 482.13(a)(1)(ii) which would require that the hospital inform all Medicare beneficiaries by written notice, at the time of inpatient admission or outpatient service, of their right to file a written complaint about the quality of care they are receiving or have received to the QIO in the State where services are being or were provided. In addition, the new standard would require the hospital to provide beneficiaries with the name, telephone number, electronic mail address, and mailing address of the QIO, as well as require that the hospital document in the beneficiary's record that it has presented the written notice to the beneficiary or beneficiary's representative or surrogate.

D. Requirements for Long Term Care Facilities (§ 483.10)

Section 1819(a) of the Act defines a skilled nursing facility (SNF) for Medicare purposes as an institution or a distinct part of an institution that is primarily engaged in providing skilled nursing care and related services to residents that require medical or nursing care or rehabilitation services due to an injury, disability, or illness. Section 1919(a) of the Act defines a nursing facility (NF) for Medicaid purposes as an institution or a distinct part of an institution that is primarily engaged in providing to residents: Skilled nursing care and related services for residents who require medical or nursing care; rehabilitation services due to an injury, disability, or illness; or, on a regular basis, health-related care and services to individuals who, due to their mental or physical condition, require care and services (above the level of room and board) that are available only through an institution.

To participate in the Medicare and Medicaid programs, long-term care (LTC) facilities, that is, SNFs and NFs, must meet certain Federal requirements specified at § 483.1 through § 483.75. SNFs must be certified as meeting the requirements of section 1819(a) through section (d) of the Act. NFs must be certified as meeting the requirements in section 1919(a) through section (d) of the Act.

LTC facilities provide a substantial amount of care to Medicare beneficiaries and Medicaid recipients, as well as "dual eligibles," who qualify for both Medicare and Medicaid. As of December 2008, there were 15,727 LTC facilities and each year they provided care for about 1.7 million individuals. In 2007, SNFs and NFs accounted for more than 10 and 15 percent, respectively, of Medicare and Medicaid expenditures.

The current regulation for LTC facilities contains specific requirements that address resident rights. However, it does not require LTC facilities to inform beneficiaries of their right to communicate with a QIO. Therefore, we are proposing to revise the resident rights requirements at § 483.10 by redesignating paragraphs (c) through (o) as paragraphs (d) through (p). We are proposing to add a new standard at paragraph (c). The proposed new standard would require the LTC facility to inform all Medicare beneficiaries by written notice, at the time of admission, of their right to file a written complaint with the QIO in the State where services

are being or were provided about the quality of care they are receiving or have received. In addition, the proposed new standard would require the LTC facility to provide the beneficiary with the name, telephone number, electronic mail address, and mailing address of the QIO, as well as require that the LTC facility document in the beneficiary's record that it has presented the written notice to the beneficiary or his or her representative or surrogate.

E. Home Health Agencies (§ 484.10)

Under sections 1861(m), 1861(o), and 1891 of the Act, the Secretary has established in regulations the requirements that a Home Health Agency (HHA) must meet in order to participate in the Medicare program. Home health services are covered for the elderly and disabled under the Hospital Insurance (Part A) and Supplemental Medical Insurance (Part B) benefits of the Medicare program. These services must be furnished by, or under arrangement with, a HHA that participates in the Medicare program and, as a general rule, must be provided on a visiting basis in the beneficiary's home.

As of December 2008, there were 9,787 HHAs participating in the Medicare program. Medicare-certified HHAs provided home health services to 3.2 million patients nationwide in FY 2006. The effective delivery of quality home health services is essential to the care and prevention of recurrent illness and hospitalizations.

The home health services CoPs requirements are located at § 484.1 through § 484.55. Currently the patient rights standard for HHAs specifies that the HHA must provide the patient with a written notice of the patient's rights in advance of furnishing care to the patient or during the initial evaluation visit before the initiation of treatment. To further assist with improving quality of health care, we are proposing to revise the HHA patient rights requirement at § 484.10 by redesignating paragraphs (c) through paragraphs (f) as paragraphs (d) through paragraphs (g). We are also proposing to add a new standard at paragraph (c). The proposed new standard would require the HHA to inform all Medicare beneficiaries by written notice, at the time of initiation of treatment, of their right to file a written complaint about the quality of care they are receiving or have received to the QIO in the State where services are being or were provided. In addition, the proposed standard would require the HHA to provide the beneficiary with the name, telephone number, electronic mail address, and mailing address of the QIO, and to document in the beneficiary's record that the written notice was presented to the beneficiary or beneficiary's representative or surrogate.

F. Comprehensive Outpatient Rehabilitation Facilities (§ 485.56)

Section 1861(cc) of the Act defines the term "comprehensive outpatient rehabilitation facility" (CORF) and lists the requirements that a CORF must meet to be eligible for Medicare participation. By definition, under 42 CFR 485.51(a), a CORF is a non-residential facility that is established and operated exclusively for the purpose of providing diagnostic, therapeutic, and restorative services to outpatients for the rehabilitation of injured, disabled, or sick persons, at a single fixed location, by or under the supervision of a physician. As of December 2008, there were 476 Medicare-certified CORFs in the United States.

Section 1861(cc)(2)(J) of the Act also states that the CORF must meet other requirements that the Secretary finds necessary in the interest of the health and safety of a CORF's patients. Under this authority, the Secretary has established requirements at § 485.50 through § 485.74, that a CORF must meet to participate in the Medicare program.

We are proposing to amend the governing body and administration requirements at § 485.56 by adding a new requirement at paragraph (e)(11). We are also proposing to add a new standard by adding a new paragraph (g). At proposed paragraph (e)(11), we are proposing to require that CORFs provide patients with the mailing address, electronic mail address, and telephone number of the State survey agency to report complaints. The proposed new standard in paragraph (g) would require the CORF to inform all Medicare beneficiaries by written notice, at the time of initiation of treatment, of their right to file a written complaint about the quality of care they are receiving or have received to the QIO in the State where services are being or were provided. In addition, the proposed standard would require the CORF to provide the beneficiary with the name, telephone number, electronic mail address, and mailing address of the QIO, and document in the beneficiary's record that it has presented the written notice to the beneficiary or beneficiary's representative or surrogate.

G. Critical Access Hospitals (§ 485.627)

Sections 1820 and 1861(mm) of the Act provide that critical access hospitals participating in Medicare and Medicaid meet certain specified requirements. CMS has implemented these provisions in 42 CFR part 485, subpart F, Conditions of Participation for Critical Access Hospitals (CAHs). There are 1,305 CAHs that must meet the CAH CoPs. CAHs are small, generally rural, limited-service facilities with low patient volume. The intent of designating facilities as "critical access hospitals" is to preserve access to primary care and emergency services that meet community needs. A CAH designation is a core component of the State's Medicare Rural Hospital Flexibility Program (Flex Program). To be designated as a CAH, a facility must be located in a State that has established a Flex program, be located in a rural area or be treated as rural in accordance with existing § 485.610(b), which, among other things, allows qualified hospital providers in urban areas to be treated as rural for purposes of becoming a CAH. Facilities that are so designated and meet the CAH conditions of participation (CoPs) under 42 CFR part 485, subpart F, will be certified as CAHs by CMS.

The current regulations at § 485.601 through § 485.647 do not contain patient rights requirements. Therefore, we are proposing to revise the organizational structure requirements by adding two new standards at § 485.627(c) and (d). The first proposed standard would require the CAH to provide CAH patients with the mailing address, electronic mail address, and telephone number of the State survey agency if the patient wishes to report complaints. The second proposed standard would require the CAH to inform all Medicare beneficiaries by written notice, at the time of service, of their right to file a written complaint with the QIO in the State where services are being or were provided about the quality of care they are receiving or have received. In addition, the new standard would require the CAH to provide the beneficiary with the name, telephone number, electronic mail address, and mailing address of the QIO, and to document in the beneficiary's record that the CAH has presented the written notice to the beneficiary or beneficiary's representative or surrogate.

H. Clinics and Rehabilitation Agencies, and Public Health Agencies as Providers of Outpatient Physical Therapy and Speech-Language Pathology Services (§ 485.709)

Under section 1861(p) of the Act, the Secretary has established CoPs that clinics and rehabilitation agencies must meet when they provide outpatient physical therapy (OPT) and speech-

language pathology services. Section 1861(p) of the Act describes "outpatient physical therapy services" to mean physical therapy services furnished by a provider of services, a clinic or rehabilitation agency, or by others under an arrangement with, and under the supervision of, such provider, clinic or rehabilitation agency to an individual as an outpatient. The patient must also be under the care of a physician.

The term also includes speech-language pathology services furnished by a provider of services, a clinic, or a rehabilitation agency, or by others under an arrangement. There are 2,781 Medicare certified clinics and rehabilitation agencies that provide outpatient physical therapy and speech-language pathology services.

The current regulations at § 485.701 through § 485.729 do not contain patient rights requirements, therefore, we are proposing to revise the administrative management requirements by adding two new standards at § 485.709(e) and § 485.709(f). The first proposed standard would require that the clinic or rehabilitation agency provide all patients with the mailing address, electronic mail address, and telephone number of the State survey agency in order to permit patients to report complaints. The second proposed standard would require the clinics or rehabilitation agencies to inform all Medicare beneficiaries by written notice, at the time of initiation of treatment, of their right to file a written complaint with the QIO in the State where services are being or were provided about the quality of care they are receiving or have received. In addition, the new standard would require the facility to provide the beneficiary with the name, telephone number, electronic mail address, and mailing address of the QIO, and would require that clinics or rehabilitation agencies document in the beneficiary's record that they have presented the written notice to the beneficiary or beneficiary's representative or surrogate.

I. Portable X-Ray Services (§ 486.100)

The Conditions for Coverage (CfC) for portable x-ray services are specified under section 1861(s)(3) of the Act and were adopted in January 1969. X-ray services are provided under the supervision of a qualified physician. Diagnostic x-ray services furnished by a portable x-ray supplier are covered under Medicare when furnished in a place of residence used as the patient's home. Suppliers of portable x-ray services must conform to the requirements specified at § 486.100 through § 486.110.

We are proposing to amend the requirements at § 486.106 by adding new standards at § 486.106(d) and (e). The first proposed new standard would require suppliers of portable x-ray services to provide patients with the mailing address, electronic mail address, and telephone number of the State survey agency to report complaints. The second proposed standard would require the suppliers to inform all Medicare beneficiaries by written notice, at the time services are provided, of their right to file a written complaint with the QIO in the State where services are being or were provided about the quality of care they are receiving or have received. In addition, the new standard would require the supplier to provide beneficiaries with the name, telephone number, electronic mail address, and mailing address of the QIO, and to document in the beneficiary's record that they presented written notice to the beneficiary or beneficiary's representative or surrogate.

J. Rural Health Clinics: Conditions for Certification; and FQHCs Conditions for Coverage (§ 491.9)

Rural Health Clinics (RHCs) and Federally Qualified Health Centers (FQHCs) under section 1861(aa) of the Act were established to improve and maintain primary care for rural and underserved communities. To qualify as an RHC, a facility must be located in a medically underserved area (MUA), a health professional shortage area (HPSA) either by population or geographic area or location, or a State Governor-designated shortage area. To qualify as an FQHC, a facility may be located in either an urban or rural area. The distinction between urban and rural is based on whether or not the area in which a clinic is located is part of a Metropolitan Statistical Area.

Primary health care services for RHCs and FQHCs are defined as the treatment of acute or chronic medical problems which usually brings a patient to a physician's office. An RHC may be any primary care practice (for example, family practice, pediatric, obstetrics, gynecology, or internal medicine). An FQHC must provide primary care for all life-cycle ages. Therefore, primary care specialty practices are not eligible for FQHC status unless they provide primary care for all life-cycles. The FQHC program is funded under Section 330 of the Public Health Service Act.

RHCs and FQHCs improve access to primary health care in rural or underserved communities and promote a collaborative model of health care delivery using physicians and non-physician practitioners. Currently, there are 3,758 Medicare-approved RHCs and approximately 4,384 FQHCs. To qualify for Medicare reimbursement, RHCs and FQHCs must comply with conditions for certification and CfCs, respectively, at CFR part 491, subpart A. The current conditions for RHCs and FQHCs, are located at § 491.1 through § 491.11.

We are proposing to revise the provision of services condition at § 491.9 by adding two new standards at § 491.9(e) and (f). The first proposed new standard would require the clinic or center to provide all patients with the mailing address, electronic mail address, and telephone number of the State survey agency in order to allow patients to report complaints. The second proposed standard would require RHCs and FQHCs to inform all Medicare beneficiaries by written notice, at the time of service, of their right to file a written complaint with the QIO in the State where services are being or were provided about the quality of care they are receiving or have received. In addition, the RHC or FQHC would be required to provide beneficiaries with the name, telephone number, electronic mail address, and mailing address of the QIO, and to document in the beneficiary's record that they have presented the written notice to the beneficiary or beneficiary's representative or surrogate.

IV. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995 (PRA), we are required to provide 60-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(a) of the PRA requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

We are soliciting public comment on each of these issues for the following sections of this document:

A. ICRs Regarding Condition for Coverage: Patient Rights—Ambulatory Surgical Centers (ASCs) (§ 416.50)

Proposed § 416.50(c)(1) would require that at the time of admission, an ASC must inform all Medicare beneficiaries by written notice of their right to file a written complaint with the QIO in the State where services are being or were provided about the quality of care they are receiving or have received. Proposed § 416.50(c)(3) would require the ASC to document that the written notice was presented to the beneficiary, beneficiary's representative or surrogate. The burden associated with these requirements is the time and effort associated with developing and distributing a standard written notice and documenting receipt of the notice.

We believe 5,174 ASCs must comply with these requirements. We estimate that proposed § 416.50 will impose a one-time 2 hour burden for the development of a standard written notice containing the name, address, and telephone number of the QIO. The total burden associated with this task is 10,348 hours. Similarly, we estimate that each ASC will distribute approximately 1,224 notices per year for a total of 6,332,976 annual notices. We estimate that it will take a total of 5 minutes to notify the beneficiary, beneficiary's representative or surrogate and to document distribution of the notification. The estimated annual burden for this requirement is 527,748 hours. The total estimated annual burden associated with all of the requirements in proposed § 416.50 is 538,096 hours. The total cost associated with this requirement is $18,978,232.

B. ICRs Regarding Condition of Participation: Patient's Rights—Hospices (§ 418.52)

Proposed § 418.52(c)(9) would require that hospices provide patients with the address and telephone number of the State survey agency to report complaints. Proposed § 418.52(d)(1) would require that at the time of admission, a hospice must inform all Medicare beneficiaries by written notice of their right to file a written complaint to the QIO in the State where services are being or were provided about the quality of care they are receiving or have received. Proposed § 418.52(d)(3) would require the hospice to document that the written notice was presented to the beneficiary, the beneficiary's representative or surrogate. The burden associated with these requirements is the time and effort associated with developing and distributing a standard written notice and documenting the receipt of the notice.

We believe 3,346 hospice facilities must comply with these requirements. We estimate that proposed § 418.52 will impose a one-time 2-hour burden for the development of a standard written notice containing the address and telephone number of the State survey agency and the name, address, and telephone number of the QIO. The total burden associated with this task is 6,692 hours. Similarly, we estimate that each hospice will distribute approximately 314 notices per year for a total of 1,050,644 annual notices. We estimate that it will take a total of 5 minutes to notify the beneficiary, the beneficiary's representative or surrogate and to document the distribution of the notice. The estimated annual burden for this requirement is 87,554 hours. The total estimated annual burden associated with all of the requirements in proposed § 418.52 is 94,246 hours. The total cost associated with this requirement is $3,392,298.

C. ICRs Regarding Patients Rights—Hospitals (§ 482.13)

Proposed § 482.13(a)(1)(i) would require that hospitals provide patients with the address and telephone number of the State survey agency to report complaints. We believe a total of 4,859 hospitals must comply with this requirement. We estimate that proposed § 482.13 will impose a one-time one hour burden for the development of a standard written notice containing the address and telephone number of the State survey agency. The total burden associated with this task is 4,859 hours at a cost of $238,091. This notice can be incorporated into existing admission paperwork documents that are already required and given to the beneficiary, beneficiary's representative or surrogate, therefore we are not assigning additional burden hours.

Proposed § 482.13(a)(1)(ii) would require that at the time of inpatient admission or outpatient service, the hospital must inform all Medicare beneficiaries by written notice of their right to file a written complaint with the QIO in the State where services are being or were provided about the quality of care they are receiving or have received.

Proposed § 482.13(a)(1)(ii) would also require the hospital to document that the written notice was presented to the beneficiary, beneficiary's representative or surrogate. The burden associated with these requirements is the time and effort associated with developing and distributing a standard written notice and documenting the distribution of the notice.

We believe 4,859 hospitals must comply with these requirements. We estimate that proposed § 482.13 will impose a one-time two hour burden for the development of a standard written notice containing the name, address, and telephone number of the QIO. The total burden associated with this task is 9,718 hours. Similarly, we estimate that each hospital will distribute approximately 228 notices per year for a total of 1,107,852 annual notices. We estimate that it will take a total of 5 minutes to notify the beneficiary, the beneficiary's representative or surrogate and to document the distribution of the notice. The estimated annual burden for this requirement is 92,321 hours at a cost of $3,231,235. The total estimated annual burden associated with all of the requirements in proposed § 482.13 is 102,039 hours. The total cost associated with this requirement is $3,707,417.

D. ICRs Regarding Resident Rights—Long Term Care Facilities (§ 483.10)

Proposed § 483.10(c)(1) would require that at the time of admission, a LTC facility must inform all Medicare beneficiaries by written notice of their right to file a written complaint with the QIO in the State where services are being or were provided about the quality of care they are receiving or have received. Proposed § 483.10(c)(3) would require the LTC facility to document that the written notice was presented to the beneficiary, beneficiary's representative or surrogate. The burden associated with these requirements is the time and effort associated with developing and distributing a standard written notice and documenting the distribution of the notice.

We believe 15,727 LTC facilities must comply with these requirements. We estimate that proposed § 483.10 will impose a one-time 2 hour burden for the development of a standard written notice containing the name, address, and telephone number of the QIO. The total burden associated with this task is 31,454 hours. Similarly, we estimate that each LTC facility will distribute approximately 89 notices per year for a total of 1,399,703 annual notices. We estimate that it will take a total of 5 minutes to notify the beneficiary, the beneficiary's representative or surrogate and to document the distribution of the notice. The estimated annual burden for this requirement is 116,642 hours. The total estimated annual burden associated with all of the requirements in proposed § 483.10 is 148,096 hours. The total cost associated with this requirement is $5,623,716.

E. ICRs Regarding Condition of Participation: Patient Rights—Home Health Agencies (§ 484.10)

Proposed § 484.10(c)(1) would require that at the time of initiation of treatment, an HHA must inform all Medicare beneficiaries by written notice of their right to file a written complaint with the QIO in the State where services are being or were provided about the quality of care they are receiving or have received. Proposed § 484.10(c)(3) would require the HHA to document that the written notice was presented to the beneficiary, beneficiary's representative or surrogate. The burden associated with these requirements is the time and effort associated with developing and distributing a standard written notice and to document the distribution of the notice.

We believe 9,787 HHAs must comply with these requirements. We estimate that proposed § 484.10 will impose a one-time 2 hour burden for the development of a standard written notice containing the name, address, and telephone number of the QIO. The total burden associated with this task is 19,574 hours. Similarly, we estimate that each HHA will distribute approximately 625 notices per year for a total of 6,116,875 annual notices. We estimate that it will take a total of 5 minutes to notify the beneficiary, beneficiary's representative or surrogate and to document the distribution of the notice. The estimated annual burden for this requirement is 509,739 hours. The total estimated annual burden associated with all of the requirements in proposed § 484.10 is 529,313 hours. The total cost associated with this requirement is $18,799,991.

F. ICRs Regarding Condition of Participation: Governing Body and Administration—Comprehensive Outpatient Rehabilitation Facilities (§ 485.56)

Proposed § 485.56(e)(11) would require that the CORF provide patients with the address and telephone number of the State survey agency to report complaints. Proposed § 485.56(g)(1) would require that at the time of initiation of treatment, a CORF must inform all Medicare beneficiaries by written notice of their right to file a written complaint to the QIO in the State where services are being or were provided about the quality of care they are receiving or have received. Proposed § 485.56(g)(3) would require the CORF to document that the written notice was presented to the beneficiary, beneficiary's representative or surrogate. The burden associated with these requirements is the time and effort associated with developing and distributing a standard written notice and documenting the distribution of the notice.

We believe 476 CORFs must comply with these requirements. We estimate that proposed § 485.56 will impose a one-time 2 hour burden for the development of a standard written notice containing the address and telephone number of the State survey agency and the name, address, and telephone number of the QIO. The total burden associated with this task is 952 hours. Similarly, we estimate that each CORF will distribute approximately 13 notices per year for a total of 6,118 annual notices. We estimate that it will take a total of 5 minutes to notify the beneficiary, the beneficiary's representative or surrogate and to document distribution of the notice. The estimated annual burden for this requirement is 516 hours. The total estimated annual burden associated with all of the requirements in proposed § 485.56 is 1,468 hours. The total cost associated with this requirement is $64,708.

G. ICRs Regarding Condition of Participation: Organizational Structure—Critical Access Hospitals (§ 485.627)

Proposed § 485.627(c) would require that the CAHs provide all patients with the address and telephone number of the State survey agency to report complaints. Proposed § 485.627(d)(1) would require that at the time of service, the CAH must inform all outpatient Medicare beneficiary patients by written notice of their right to file a written complaint to the QIO in the State where services are being or were provided about the quality of care they are receiving or have received. Proposed § 485.627(d)(3) would require the CAH to document that the written notice was presented to the beneficiary, beneficiary's representative or surrogate. The burden associated with these requirements is the time and effort associated with developing and distributing a standard written notice and documenting the distribution of the notice.

We believe a total of 1310 CAHs must comply with these requirements. We estimate that proposed § 485.627 will impose a one-time 2 hour burden for the development of a standard written notice containing the address and telephone number of the State survey agency and the name, address, and telephone number of the QIO. The total burden associated with this task is 2620 hours. Similarly, we estimate that each CAH will distribute approximately 1000 notices per year for a total of 1,310,000 annual notices. We estimate that it will take a total of 5 minutes to notify the beneficiary, the beneficiary's representative or surrogate and to document distribution of the notice for a total annual burden of 109,167. The estimated annual burden associated with all of the requirements in proposed § 485.627 is 111,787 hours. The total cost associated with this requirement is $3,949,225.

H. ICRs Regarding Condition of Participation: Administrative Management—Clinic and Rehabilitation Agencies (§ 485.709)

Proposed § 485.709(e) would require that the clinic or rehabilitation agency provide patients with the address and telephone number of the State survey agency to report complaints. Proposed § 485.709(f)(1) would require that at the time of initiation of treatment, the clinic or rehabilitation agency must inform all Medicare beneficiaries by written notice of their right to file a written complaint with the QIO in the State where services are being or were provided about the quality of care they are receiving or have received. Proposed § 485.709(f)(3) would require the clinic, or rehabilitation agency to document that the written notice was presented to the beneficiary, beneficiary's representative or surrogate. The burden associated with these requirements is the time and effort associated with developing and distributing a standard written notice and documenting the distribution of the notice.

We believe a total of 2,781 clinics and rehabilitation agencies must comply with these requirements. We estimate that proposed § 485.709 will impose a one-time 2 hour burden for the development of a standard written notice containing the address and telephone number of the State survey agency and the name, address, and telephone number of the QIO. The total burden associated with this task is 5,562 hours. Similarly, we estimate that each clinic or rehabilitation agency will distribute approximately 1,084 notices per year for a total of 3,014,604 annual notices. We estimate that it will take a total of 5 minutes to notify the beneficiary, the beneficiary's representative or surrogate and to document distribution of the notice. The estimated annual burden for this requirement is 251,217 hours at a cost of $8,792,595. The total estimated annual burden associated with all of the requirements in proposed § 485.709 is 256,779 hours. The total cost associated with this requirement is $9,065,133.

I. ICRs Regarding Condition for Coverage: Referral for service and preservation of records—Portable X-ray Services (§ 486.106)

Proposed § 486.106(d) would require that the supplier of portable x-ray services provide patients with the address and telephone number of the State survey agency to report complaints. Proposed § 486.106(e)(1) would require that at the time that services are provided, a supplier of portable x-ray services must inform all Medicare beneficiaries by written notice of their right to file a written complaint about the quality of care they are receiving or have received to the QIO in the State where services are being or were provided. Proposed § 486.106(e)(3) would require the supplier of portable x-ray services to document that the written notice was presented to the beneficiary, beneficiary's representative or surrogate. The burden associated with these requirements is the time and effort associated with developing and distributing a standard written notice and documenting the distribution of the notice.

We believe 547 suppliers of portable x-ray services must comply with these requirements. We estimate that proposed § 486.106 will impose a one-time 2 hour burden for the development of a standard written notice containing the address and telephone number of the State survey agency and the name, address, and telephone number of the QIO. The total burden associated with this task is 1,094 hours at a cost of $53,606. Similarly, we estimate that each supplier of portable x-ray services will distribute approximately 2,437 notices per year for a total of 1,333,039 annual notices. We estimate that it will take a total of 5 minutes to notify the beneficiary, the beneficiary's representative or surrogate and to document distribution of the notice. The estimated annual burden for this requirement is 111,086 hours at a cost of $3,888,010. The total estimated annual burden associated with all of the requirements in proposed § 486.106 is 112,180 hours. The total cost associated with this requirement is $3,941,616.

J. ICRs Regarding Provision of Services—Rural Health Clinics or Federally Qualified Health Centers (§ 491.9)

Proposed § 491.9(e) would require that the RHC or FQHC provide patients with the address and telephone number of the State survey agency to report complaints. Proposed § 491.9(f)(1) would require that at the time of service, an RHC or FQHC must inform all Medicare beneficiaries by written notice of their right to file a written complaint with the QIO in the State where services are being or were provided about the quality of care they are receiving or have received. Proposed § 491.9(f)(3) would require the RHC or FQHC to document that the written notice was presented to the beneficiary, beneficiary's representative or surrogate. The burden associated with these requirements is the time and effort associated with developing and distributing a standard written notice and documenting the distribution of the notice.

We believe a total of 8,142 RHCs or FQHCs must comply with these requirements. We estimate that proposed § 491.9 will impose a one-time 2 hour burden for the development of a standard written notice containing the address and telephone number of the State survey agency to report complaints and the name, address, and telephone number of the QIO. The total burden associated with this task is 16,284 hours at a cost of $797,916. Similarly, we estimate that each RHC or FQHC will distribute approximately 8 notices per year for a total of 65,136 annual notices. We estimate that it will take a total of 5 minutes to notify the beneficiary, the beneficiary's representative or surrogate and to document distribution of the notice. The estimated annual burden for this requirement is 5,428 hours at a cost of $189,980. The total estimated annual burden associated with all of the requirements in proposed § 491.9 is 21,712 hours. The total cost associated with this requirement is $987,896.

TABLE 1—ESTIMATED ANNUAL BURDEN FOR RECORDKEEPING AND REPORTING REQUIREMENTS

Regulation section	OMB Control No.	Respondents	Responses	Burden per response (hours)	Total annual burden (hours)	Hourly labor cost of reporting ($)	Total labor cost of reporting ($)	Total capital/ maintenance costs ($)	Total costs ($)
§ 416.50(c)(1)	0938–New	5,174	5,174	2	10,348	49	507,052	0	507,052
§ 416.50(c)(3)	0938–New	5,174	6,332,976	.0833	527,748	35	18,471,180	0	18,471,180
§ 418.52(c)(9) & (d)(1).	0938–New	3,346	3,346	2	6,692	49	327,908	0	327,908
§ 418.52(d)(3)	0938–New	3,346	1,050,644	.0833	87,554	35	3,064,390	0	3,064,390
§ 482.13(a)(i)	0938–New	4,859	4,859	1	4,859	49	238,091	0	238,091
§§ 482.13(a)(1)(ii)	0938–New	4,859	4,859	2	9,718	49	476,182	0	476,182
§ 482.13(a)(1)(ii)	0938–New	4,859	1,107,852	.0833	92,321	35	3,231,235	0	3,231,235
§ 483.10(c)(1)	0938–New	15,727	15,727	2	31,454	49	1,541,246	0	1,541,246
§ 483.10(c)(3)	0938–New	15,727	1,399,703	.0833	116,642	35	4,082,470	0	4,082,470
§ 484.10(c)(1)	0938–New	9,787	9,787	2	19,574	49	959,126	0	959,126
§ 484.10(c)(3)	0938–New	9,787	6,116,875	.0833	509,739	35	17,840,865	0	17,840,865
§ 485.56(e)(11) & (g)(1).	0938–New	476	476	2	952	49	46,648	0	46,648
§ 485.56(g)(3)	0938–New	476	6,188	.0833	516	35	18,060	0	18,060
§ 485.627(c) & (d)(1).	0938–New	1,310	1,310	2	2,620	49	128,380	0	128,380
§ 485.627(d)(3) ...	0938–New	1,310	1,310,000	.0833	109,167	35	3,820,845	0	3,820,845
§ 485.709(e) & (f)(1).	0938–New	2,781	2,781	2	5,562	49	272,538	0	272,538
§ 485.709(f)(3)	0938–New	2,781	3,014,604	.0833	251,217	35	8,792,595	0	8,792,595
§ 486.106(d) & (e)(1).	0938–New	547	547	2	1,094	49	53,606	0	53,606
§ 486.106(e)(3) ...	0938–New	547	1,333,039	.0833	111,086	35	3,888,010	0	3,888,010
§ 491.9(e) & (f)(1)	0938–New	8,142	8,142	2	16,284	49	797,916	0	797,916
§ 491.9(f)(3)	0938–New	8,142	65,136	.0833	5,428	35	189,980	0	189,980
Total	.....	52,149	21,794,025	.....	1,920,575	.....	.....	.....	68,748,323

We have submitted a copy of this proposed rule to OMB for its review of the information collection requirements contained within this document. These requirements are not effective until they are approved by OMB.

If you comment on these information collection and recordkeeping requirements, please do either of the following:

1. Submit your comments electronically as specified in the **ADDRESSES** section of this proposed rule; or

2. Submit your comments to the Office of Information and Regulatory Affairs, Office of Management and Budget, Attention: CMS Desk Officer, CMS–3225–P; Fax: (202) 395–6974; or E-mail: *OIRA_submission@omb.eop.gov.*

V. Response to Comments

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this preamble, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

VI. Regulatory Impact Statement (or Analysis)

A. Overall Impact

We have examined the impact of this rule as required by Executive Order 12866 (September 1993, Regulatory Planning and Review), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Social Security Act, the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4), and Executive Order 13132.

Executive Order 12866 (as amended by Executive Order 13258, which merely reassigns responsibility of duties) directs agencies to assess all costs and benefits or available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more in any 1 year). We have examined the impact of this proposed rule, and we have determined that this rule is neither expected to meet the criteria to be considered economically significant, nor do we believe it will meet the criteria for a major rule.

This proposed rule would set forth new requirements for certain Medicare certified providers and suppliers that do not provide hospital in-patient care. This rule will implement regulations that are intended to increase awareness by Medicare beneficiaries of their right to contact the QIO in their State about the quality of care they are currently receiving or have received. In addition, the Medicare certified providers and suppliers would be required to provide their Medicare beneficiaries with written notice of the QIOs contact information, and document that the written notice was presented to the beneficiary, beneficiary's representative or surrogate. The RFA requires agencies to analyze options for regulatory relief of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small government jurisdictions. Individuals and States are not included in the definition of small entity. Most Medicare certified providers and suppliers are small entities, either by nonprofit status or by having revenues of $6 million to $29 million in any 1 year. For purposes of the RFA, most entities affected by this proposed rule are considered small businesses according to the Small Business Administration's size standards, with total revenues of $29 million or less in any 1 year (for details, see 65 FR 96432). We are not preparing analyses for either the RFA or section 1102(b) of the Act because we have determined, and we certify, that this rule will not have a significant economic impact on a substantial number of small entities or a significant impact on the operations of a substantial number of small rural facilities.

Section 202 of the unfunded Mandates Reform Act of 1995 also requires that agencies assess anticipated costs and benefits before issuing any rule that may result in expenditures in any year by state, local or tribal governments, in the aggregate, or by the private sector, of $120 million. This rule has no impact on the expenditures of State, local, or tribal governments, and the impact on the private sector is estimated to be less than $120 million.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications. This rule will not have any effect on State and local governments and does not have any Federalism implications.

B. Anticipated Effects

As described in the preamble, the proposed regulation will require ten different Medicare certified providers and suppliers to notify their Medicare beneficiaries by written notice of their right to contact the QIO in the State where services are being or were provided about the quality of care they are receiving or have received. Six of the eleven Medicare certified providers and suppliers that would be affected by this proposed rule already have a current patient rights condition that would be amended by this proposed rule. We believe that those Medicare certified providers and suppliers will be able to incorporate the proposed requirements into their normal business practices, and that the requirements will not present a significant additional workflow burden.

All Medicare certified providers and suppliers covered by this proposed rule would have to meet the notification of QIO rights standard by informing Medicare beneficiaries by written notice at the start of care (or for some providers or suppliers, at the time of inpatient admission or at an initial assessment visit in advance of furnishing care) of their right to file a written complaint to the QIO in the State where services are being or were provided regarding the quality of care they are receiving or have received. The written notice must contain the name of the QIO, its mailing address, electronic address and telephone number.

We recognize that in describing the effect of this rule on the different Medicare certified providers and suppliers, suggested burden estimates may not accurately reflect the experience of all of them. Facilities vary in the complexity of operations and processes, and therefore, associated costs may differ.

Table 2 contains data that is frequently used in this impact statement. The salary-related cost data is referenced from the *Salarywizard.com* Web site at *http://hrsalarycenter.salary.com.*

TABLE 2—ASSUMPTIONS AND ESTIMATES USED THROUGHOUT THE IMPACT ANALYSIS SECTION

Provider or supplier type	Number of providers or suppliers	Estimated annual Medicare beneficiary notifications
Clinics, Rehab agencies, Outpatient Physical Therapy	2,781	3,014,604
Comprehensive Outpatient Rehabilitation Facilities	476	6,188
Home Health Agencies	9,787	6,116,875
Hospices	3,346	1,050,644
Long Term Care Facilities	15,727	1,399,703
Hospitals	4,859	1,107,852
Critical Access Hospitals	1,310	1,310,000
Ambulatory Surgical Centers	5,174	6,332,976
Portable X-ray Services	547	1,333,039
Rural Health Clinics and Federally Qualified Health Centers	8,142	65,136

Job description/title	Hourly rate
Administrator	$49
Registered Nurse	35

Note: All salary estimates include a benefits package worth 30% of the fringe base salary.

We estimate that an administrator, earning $49.00 per hour, would be largely responsible for developing the written notice and ensuring the accuracy of the information that will be given to Medicare beneficiaries. We believe that Medicare certified providers and suppliers will use the approved Federal IM notice as an example to develop their written notice in order to avoid time spent on re-creating a similar document. We estimate that the one-time cost for one provider or supplier to develop and implement Medicare beneficiary notification of QIO rights and State agency contact information will be approximately 2 hours at $49.00 per hour for a total cost of $98.00.

We estimate that it will take a registered nurse approximately five minutes to provide each Medicare beneficiary with the written notice and document that the written notice was presented to the beneficiary, beneficiary's representative or surrogate. At the average hourly rate for a registered nurse ($35.00), it will cost $3 per patient to fulfill the requirement. The total cost to implement the requirement of presenting and documenting the written QIO notice to the Medicare Beneficiary for all ten Medicare certified providers and suppliers would be $68,748,323. 2 hours × $49 an hour = $98. $35 hour/60 minutes = $0.58 minutes × 5 minutes = $3.

TABLE 3—MEDICARE BENEFICIARY NOTIFICATION OF QIO RIGHTS BURDEN ASSESSMENT

Provider or supplier type	Time per patient (min.)	Time for all patients (hours)	Cost per patient	Cost for all patients
Clinics, Rehab Agencies, Outpatient Physical Therapy	5	251,117	$3.00	$9,065,133
Critical Access Hospitals	5	109,167	3.00	3,949,225
Comprehensive Outpatient Rehabilitation Facilities	5	516	3.00	64,708
Home Health Agencies	5	509,739	3.00	18,799,991
Hospices	5	87,554	3.00	3,392,298
Hospitals	5	92,231	3.00	3,707,417
Long term Care Facilities	5	116,642	3.00	5,623,716
Ambulatory Surgical Centers	5	527,748	3.00	18,978,232
Portable X-ray Services	5	111,086	3.00	3,941,616
Rural Health Clinics & Federally Qualified Health Centers	5	5,428	3.00	987,896
Total Cost (including one-time development of the QIO written notice) ..	N/A	N/A	N/A	68,748,323

In accordance with the provisions of Executive Order 12866, this regulation was reviewed by the Office of Management and Budget.

List of Subjects

42 CFR Part 416

Health facilities, Health professions, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 418

Health facilities, Hospice care, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 482

Grant programs—health, Hospitals, Medicaid, Medicare, Reporting and recordkeeping requirements

42 CFR Part 483

Grant programs—health, Health facilities, Health professions, Health records, Medicaid, Medicare, Nursing homes, Nutrition, Reporting and recordkeeping requirements, Safety.

42 CFR Part 484

Health facilities, Health professions, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 485

Grant programs—health, Health facilities, Medicaid, Medicare, Reporting and recordkeeping requirements.

Critical Access Hospitals?

42 CFR Part 486

Grant programs—health, Health facilities, Medicare, Reporting and recordkeeping requirements, X-rays.

42 CFR Part 491

Grant programs—health, Health facilities, Medicaid, Medicare, Reporting and recordkeeping requirements, Rural areas.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services propose to amend 42 CFR chapter IV as set forth below:

PART 416—AMBULATORY SURGICAL SERVICES

1. The authority citation for part 416 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

Subpart C—Specific Conditions for Coverage

2. Section 416.50 is amended by redesignating paragraphs (c) and (d) as paragraphs (d) and (e), respectively, and adding a new paragraph (c) to read as follows:

§ 416.50 Condition for coverage—Patient rights.

* * * * *

(c) *Standard: Notification of the right to access a Quality Improvement Organization (QIO).* (1) At the time of admission, the ASC must inform all Medicare beneficiaries by written notice of their right to file a written complaint with the QIO in the State where services are being or were provided about the quality of care they are receiving or have received.

(2) The written notice must contain the name of the QIO, its mailing address, electronic mail address, and telephone number.

(3) The ASC must document in the beneficiary's record that the written notice was presented to the beneficiary or beneficiary's representative or surrogate.

* * * * *

PART 418—HOSPICE CARE

3. The authority citation for part 418 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

Subpart C—Conditions of Participation: Patient Care

4. Section 418.52 is amended by adding paragraphs (c)(9) and (d) to read as follows:

§ 418.52 Condition of participation: Patient's rights.

* * * * *

(c) * * *

(9) Receive the mailing address, electronic mail address, and telephone number of the State survey agency to report complaints.

(d) *Standard: Notification of the right to access a Quality Improvement Organization (QIO).* (1) During the initial assessment visit in advance of furnishing care, the hospice must inform all Medicare beneficiaries by written notice of their right to file a written complaint with the QIO in the State where services are being or were provided about the quality of care they are receiving or have received to the QIO in the State where services are being or were provided.

(2) The written notice must contain the name of the QIO, its mailing address, electronic mail address, and telephone number.

(3) The hospice must document in the beneficiary's record that the written notice was presented to the beneficiary or beneficiary's representative or surrogate.

PART 482—CONDITIONS OF PARTICIPATION FOR HOSPITALS

5. The authority citation for part 482 continues to read as follows:

Authority: Secs. 1102, 1871 and 1881 of the Social Security Act (42 U.S.C. 1302, 1395hh, and 1395rr), unless otherwise noted.

Subpart B—Administration

6. Section 482.13 is amended by adding paragraphs (a)(1)(i) and (ii) to read as follows:

§ 482.13 Condition of participation: Patients rights.

(a) * * *

(1) * * *

(i) The hospital must provide all patients with the mailing address, electronic mail address and telephone number of the State survey agency to report complaints.

(ii) At the time of inpatient admission or outpatient service, the hospital must inform all Medicare beneficiaries by written notice of their right to file a written complaint with the QIO in the State where services are being or were provided about the quality of care they are receiving or have received.

(A) The written notice must contain the name of the QIO, its mailing address, electronic mail address, and telephone number.

(B) The hospital must document in the beneficiary's record that the written notice was presented to the beneficiary or beneficiary's representative or surrogate.

PART 483—REQUIREMENTS FOR STATES AND LONG TERM CARE FACILITIES

8. The authority citation for part 483 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

Subpart B—Requirements for Long Term Care Facilities

9. Section 483.10 is amended by—

A. Redesignating paragraphs (c) through (o) as paragraphs (d) through paragraphs (p).

B. Adding a new paragraph (c).

The addition reads as follows:

§ 483.10 Resident rights.

* * * * *

(c) *Standard: Notification of the right to access a Quality Improvement Organization (QIO).* (1) At the time of admission, the LTC facility must inform all Medicare beneficiaries by written notice of their right to file a written complaint with the QIO in the State where services are being or were provided about the quality of care they are receiving or have received.

(2) The written notice must contain the name of the QIO, its mailing address, electronic mail address, and telephone number.

(3) The LTC facility must document in the beneficiary's record that the written notice was presented to the beneficiary or beneficiary's representative or surrogate.

* * * * *

PART 484—HOME HEALTH SERVICES

10. The authority citation for part 484 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395(hh)) unless otherwise indicated.

Subpart B—Administration

11. Section 484.10 is amended by—

A. Redesignating paragraphs (c) through (f) as paragraphs (d) through (g).

B. Adding a new paragraph (c).

The addition reads as follows:

§ 484.10 Condition of participation: Patient rights.

* * * * *

(c) *Standard: Notification of the right to access a Quality Improvement Organization (QIO).* (1) At the time of initiation of treatment, the HHA must inform all Medicare beneficiaries by written notice of their right to file a written complaint with the QIO in the State where services are being or were provided about the quality of care they are receiving or have received.

(2) The written notice must contain the name of the QIO, its mailing address, electronic mail address, and telephone number.

(3) The HHA must document in the beneficiary's record that the written

notice was presented to the beneficiary or beneficiary's representative or surrogate.

* * * * *

PART 485—CONDITIONS OF PARTICIPATION: SPECIALIZED PROVIDERS

12. The authority citation for part 485 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395(hh)).

Subpart B—Conditions of Participation: Comprehensive Outpatient Rehabilitation Facilities

13. Section 485.56 is amended by adding paragraphs (e)(11) and (g) to read as follows:

§ 485.56 Condition of participation: Governing body and administration.

* * * * *

(e) * * *

(11) A requirement that patients receive the mailing address, electronic mail address, and telephone number of the State survey agency to report complaints.

(g) *Standard: Notification of the right to access a Quality Improvement Organization (QIO).* (1) At the time of initiation of treatment, the CORF must inform all Medicare beneficiaries by written notice of their right to file a written complaint with the QIO in the State where services are being or were provided about the quality of care they are receiving or have received.

(2) The written notice must contain the name of the QIO, its mailing address, electronic mail address, and telephone number.

(3) The CORF must document in the beneficiary's record that the written notice was presented to the beneficiary or beneficiary's representative or surrogate.

Subpart F—Conditions of Participation: Critical Access Hospitals (CAHs)

14. Section 485.627 is amended by adding paragraphs (c) and (d) to read as follows:

§ 485.627 Condition of participation: Organizational structure.

* * * * *

(c) *Standard: Patient complaints.* The CAH must provide all hospital outpatients with the mailing address, electronic mail address and telephone number of the State survey agency to report complaints.

(d) *Standard: Notification of the right to access a Quality Improvement Organization (QIO).* (1) At the time of service, the CAH must inform all outpatient Medicare beneficiaries by written notice of their right to file a written complaint with the QIO in the State where services are being or were provided about the quality of care they are receiving or have received.

(2) The written notice must contain the name of the QIO, its mailing address, electronic mail address, and telephone number.

(3) The CAH must document in the beneficiary's record that the written notice was presented to the beneficiary or beneficiary's representative or surrogate.

Subpart H—Conditions of Participation for Clinics, Rehabilitation Agencies, and Public Health Agencies as Providers of Outpatient Physical Therapy and Speech-Language Pathology Services

15. Section 485.709 is amended by adding paragraphs (e) and (f) to read as follows:

§ 485.709 Condition of participation: Administrative management.

* * * * *

(e) *Standard: Patient complaints.* The clinic or rehabilitation agency must provide patients with the mailing address, electronic mail address, and telephone number of the State survey agency to report complaints.

(f) *Standard: Notification of the right to access a Quality Improvement Organization (QIO).* (1) At the time of initiation of treatment, the clinic or rehabilitation agency must inform all Medicare beneficiaries by written notice of their right to file a written complaint with the QIO in the State where services are being or were provided about the quality of care they are receiving or have received.

(2) The written notice must contain the name of the QIO, its mailing address, electronic mail address, and telephone number.

(3) The clinic or rehabilitation agency must document in the beneficiary's record that the written notice was presented to the beneficiary or beneficiary's representative or surrogate.

PART 486—CONDITIONS FOR COVERAGE OF SPECIALIZED SERVICES FURNISHED BY SUPPLIERS

17. The authority citation for part 486 continues to read as follows:

Authority: Secs. 1102, 1138, and 1871 of the Social Security Act (42 U.S.C. 1302, 1320b–8, and 1395hh) and section 371 of the Public Health Service Act (42 U.S.C. 273).

Subpart C—Conditions for Coverage: Portable X-Ray Services

18. Section 486.106 is amended by adding paragraphs (d) and (e) to read as follows:

§ 486.106 Condition for coverage: Referral for service and preservation of records.

* * * * *

(d) *Standard: Patient complaints.* The supplier of portable x-ray services must provide patients with the mailing address, electronic mail address, and telephone number of the State survey agency to report complaints.

(e) *Standard: Notification of the right to access a Quality Improvement Organization (QIO).* (1) At the time services are provided, the supplier of portable x-ray services must inform all Medicare beneficiaries by written notice of their right to file a written complaint with the QIO in the State where services are being or were provided about the quality of care they are receiving or have received.

(2) The written notice must contain the name of the QIO, its mailing address, electronic mail address, and telephone number.

(3) The supplier of portable x-ray services must document in the beneficiary's record that the written notice was presented to the beneficiary or beneficiary's representative or surrogate.

PART 491—CERTIFICATION OF CERTAIN HEALTH FACILITIES

19. The authority citation for part 491 continues to read as follows:

Authority: Sec. 1102 of the Social Security Act (42 U.S.C. 1302); and sec. 353 of the Public Health Service Act (42 U.S.C. 263a).

Subpart A—Rural Health Clinics: Conditions for Certification; and FQHCs Conditions for Coverage

20. Section 491.9 is amended by adding paragraphs (e) and (f) to read as follows:

§ 491.9 Provision of services.

* * * * *

(e) *Standard: Patient complaints.* The clinic or center must provide patients with the mailing address, electronic mail address, and telephone number of the State survey agency to report complaints.

(f) *Standard: Notification of the right to access a Quality Improvement Organization (QIO).* (1) At the time of service, the clinic or center must inform all Medicare beneficiaries by written notice of their right to file a written complaint with the QIO in the State where services are being or were

provided about the quality of care they are receiving or have received.

(2) The written notice must contain the name of the QIO, its mailing address, electronic mail address, and telephone number.

(3) The clinic or center must document in the beneficiary's record that the written notice was presented to the beneficiary or beneficiary's representative or surrogate.

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance; and Program No. 93.774, Medicare—Supplementary Medical Insurance Program) (Catalog of Federal Domestic Assistance Program No. 93.778, Medical Assistance Program)

Dated: August 26, 2010.

Donald M. Berwick,

Administrator, Centers for Medicare & Medicaid Services.

Approved: January 27, 2011

Kathleen Sebelius,

Secretary.

[FR Doc. 2011–2275 Filed 2–1–11; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

44 CFR Part 67

[Docket ID FEMA–2011–0002; Internal Agency Docket No. FEMA–B–1174]

Proposed Flood Elevation Determinations

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Proposed rule.

SUMMARY: Comments are requested on the proposed Base (1% annual-chance) Flood Elevations (BFEs) and proposed BFE modifications for the communities listed in the table below. The purpose of this proposed rule is to seek general information and comment regarding the proposed regulatory flood elevations for the reach described by the downstream and upstream locations in the table below. The BFEs and modified BFEs are a part of the floodplain management measures that the community is required either to adopt or to show evidence of having in effect in order to qualify or remain qualified for participation in the National Flood Insurance Program (NFIP). In addition, these elevations, once finalized, will be used by insurance agents and others to calculate appropriate flood insurance premium rates for new buildings and the contents in those buildings.

DATES: Comments are to be submitted on or before May 3, 2011.

ADDRESSES: The corresponding preliminary Flood Insurance Rate Map (FIRM) for the proposed BFEs for each community is available for inspection at the community's map repository. The respective addresses are listed in the table below.

You may submit comments, identified by Docket No. FEMA–B–1170, to Luis Rodriguez, Chief, Engineering Management Branch, Federal Insurance and Mitigation Administration, Federal Emergency Management Agency, 500 C Street, SW., Washington, DC 20472, (202) 646–4064, or (e-mail) *luis.rodriguez1@dhs.gov.*

FOR FURTHER INFORMATION CONTACT: Luis Rodriguez, Chief, Engineering Management Branch, Federal Insurance and Mitigation Administration, Federal Emergency Management Agency, 500 C Street, SW., Washington, DC 20472, (202) 646–4064, or (e-mail) *luis.rodriguez1@dhs.gov.*

SUPPLEMENTARY INFORMATION: The Federal Emergency Management Agency (FEMA) proposes to make determinations of BFEs and modified BFEs for each community listed below, in accordance with section 110 of the Flood Disaster Protection Act of 1973, 42 U.S.C. 4104, and 44 CFR 67.4(a).

These proposed BFEs and modified BFEs, together with the floodplain management criteria required by 44 CFR 60.3, are the minimum that are required. They should not be construed to mean that the community must change any existing ordinances that are more stringent in their floodplain management requirements. The community may at any time enact stricter requirements of its own or pursuant to policies established by other Federal, State, or regional entities. These proposed elevations are used to meet the floodplain management requirements of the NFIP and also are used to calculate the appropriate flood insurance premium rates for new buildings built after these elevations are made final, and for the contents in those buildings.

Comments on any aspect of the Flood Insurance Study and FIRM, other than the proposed BFEs, will be considered. A letter acknowledging receipt of any comments will not be sent.

National Environmental Policy Act. This proposed rule is categorically excluded from the requirements of 44 CFR part 10, Environmental Consideration. An environmental impact assessment has not been prepared.

Regulatory Flexibility Act. As flood elevation determinations are not within the scope of the Regulatory Flexibility Act, 5 U.S.C. 601–612, a regulatory flexibility analysis is not required.

Executive Order 12866, Regulatory Planning and Review. This proposed rule is not a significant regulatory action under the criteria of section 3(f) of Executive Order 12866, as amended.

Executive Order 13132, Federalism. This proposed rule involves no policies that have federalism implications under Executive Order 13132.

Executive Order 12988, Civil Justice Reform. This proposed rule meets the applicable standards of Executive Order 12988.

List of Subjects in 44 CFR Part 67

Administrative practice and procedure, Flood insurance, Reporting and recordkeeping requirements.

Accordingly, 44 CFR part 67 is proposed to be amended as follows:

PART 67—[AMENDED]

1. The authority citation for part 67 continues to read as follows:

Authority: 42 U.S.C. 4001 *et seq.;* Reorganization Plan No. 3 of 1978, 3 CFR, 1978 Comp., p. 329; E.O. 12127, 44 FR 19367, 3 CFR, 1979 Comp., p. 376.

§ 67.4 [Amended]

2. The tables published under the authority of § 67.4 are proposed to be amended as follows: