Supporting Statement
Medicare and Medicaid Programs: Conditions of Participation for Portable X-ray Suppliers CMS-R-43

A. Background

The purpose of this package is to request Office of Management and Budget (OMB) approval of the collection of information requirements for the conditions of participation (CoPs) that portable X-ray suppliers must meet to participate in the Medicare Program. This document represents the inclusion of all current portable X-ray supplier CoPs.

Portable X-rays are basic radiology studies (predominately chest and extremity X-rays) performed on patients in skilled nursing facilities, residents of long-term care facilities and homebound patients. The CoPs are based on criteria described in the law, and are designed to ensure that each portable X-ray supplier has properly trained staff and provides the appropriate type and level of care for patients. The information collection requirements described below are necessary to certify portable X-ray suppliers wishing to participate in the Medicare program.

B. Justification

1. Need and Legal Basis

The regulations containing these information collection requirements are located at 42 CFR 486. These regulatory requirements implement section 1395(m) of the Social Security Act (the Act). All portable X-ray suppliers must meet the CoPs in order to receive program payment for services provided to Medicare beneficiaries. We believe many of the requirements applied to portable X-ray suppliers will impose no burden since a prudent X-ray supplier would self-impose them in the normal course of doing business.

Regardless, we have attempted to estimate the associated burden for a portable X-ray supplier to engage in these standard industry practices.

2. Information Users

The information users are the suppliers and the State surveying agencies. CMS and the health care industry believe that the availability of the type of records that this regulation specifies is standard medical practice and is necessary in order to ensure the well-being and safety of patients and professional treatment accountability. CMS uses these conditions for participation to certify portable X-ray suppliers wishing to participate in the Medicare program. If CMS did not require this information, we would not be able to carry out the statutory mandate to certify only those suppliers that meet appropriate health and safety requirements.

3. Improved Information Technology

This collection does not prescribe how suppliers should prepare or maintain these records. Suppliers are free to take advantage of any technological advances that they find appropriate for their needs.

4. Duplication of Similar Information

These are unique requirements that are specified in such a way as not to duplicate existing supplier practice. If a supplier already maintains these general records, regardless of format, it is in compliance with this requirement.

5. Small Business

These requirements affect small businesses. However, the general nature of the requirements allows flexibility for suppliers to meet the requirement in a way consistent with their existing operations.

6. Less Frequent Collection

CMS does not collect this information, or require its collection, on a routine basis. Portable X-ray supplier records are reviewed at the time of a survey for initial or continued participation in the Medicare program. Less frequent information collection would impede efforts to establish compliance with the Medicare CoPs. Portable X-ray suppliers are surveyed once every five to seven years by the State survey agencies.

7. Special Circumstances

There are no special circumstances

8. Federal Register Notice/Outside Consultation

The 60-day Federal Register notice was published on April 10, 2018 (83 FR 15389).

The 30-day Federal Register notice was published on July 13, 2018 (83 FR 32667)..

9. Payment/Gift to Respondent

There are no payments or gifts associated with this collection.

10. Confidentiality

Data collected will be kept confidential to the extent provided by law. Documents related to the collection, use, or disclosure of individually identifiable or protected health information pursuant to implementing these conditions of participation are subject to the protections and standards of the Privacy Act of 1974 and the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule.

11. Sensitive Questions

There are no questions of a sensitive nature associated with this information collection.

12. Burden Estimates

Salary data is based on the U.S. Department of Labor Bureau of Labor Statistics (BLS) National Employment and Wage Data from the Occupational Employment Statistics Survey, by Occupation, found at www.bls.gov. The salary estimates contained in this package are based on the most recent data for an office administrative services staff person in 2016 and includes an assumed 100% benefits and overhead package ($32 per hour).

The recordkeeping requirements for which we are seeking approval are contained in 42 CFR sections 486.104, 486.106 and 486.110. The information is required to certify portable X-ray suppliers wishing to participate in the Medicare program. This is standard medical practice and is necessary in order to help to ensure the well-being, safety and quality professional medical treatment accountability for each patient.

The Recordkeeping Requirements

Section 486.104 - Condition for coverage: Qualifications, orientation and health of technical personnel.

(c) Standard: Employee records. Records are maintained and include evidence that --

(1) Each employee is qualified for his or her position by means of training and demonstrated competence; and

(2) Employees receive adequate health supervision.

486.104(c) -- Employee records =

.5 hour per supplier x 509 X-ray suppliers = 255 burden hours x $32/hour = $8,160

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

All portable X-ray services performed for Medicare beneficiaries are ordered by a physician or a nonphysician practitioner as provided in § 410.32(a) of this chapter or by a nonphysician practitioner as provided in § 410.32(a)(2) and records are properly preserved.

(a) Standard—Referral by a physician or nonphysician practitioner. Portable X- ray examinations are performed only on the order of a physician licensed to practice in the

State or by a nonphysician practitioner acting within the scope of State law. Such nonphysician practitioners may be treated the same as physicians treating beneficiaries for the purpose of this paragraph. The supplier's records show that:

(1) The portable X-ray test was ordered by a licensed physician or a nonphysician practitioner acting within the State scope of law; and

(2) Such physician or nonphysician practitioner's written, signed order specifies the reason a portable X-ray test is required, the area of the body to be exposed, the number of radiographs to be obtained, and the views needed; it also includes a statement concerning the condition of the patient which indicates why portable X-ray services are necessary.

(b) Standard—Records of examinations performed. The supplier makes for each patient a record of the date of the portable X-ray examination, the name of the patient, a description of the procedures ordered and performed, the referring physician or nonphysician practitioner, the operator(s) of the portable X-ray equipment who performed the examination, the physician to whom the radiograph was sent, and the date it was sent.

486.106(a)-(b) -- Referral by a physician or nonphysician practitioner and Records of examinations performed

3 minutes (.05 hour) to write an order x 3,986,000 portable X-ray exams ordered = 199,300 hours x $69/hour for a nurse = $13,751,700.

$1 for printing and faxing verbal orders to physician offices for signature x 2,500,000 verbal orders = $2,500,000

2,000,000 follow-up calls regarding the status of faxes x 10 minutes of time for clerical staff (5 minutes for portable X-ray clerical staff + 5 minutes for ordering physician clerical staff) = 333,333 hours x $32/hour = $10,666,656.

(c) Standard—Preservation of records. Such reports are maintained for a period of at least 2 years, or for the period of time required by State law for such records (as distinguished from requirements as to the radiograph itself), whichever is longer.

The requirement to preserve records is considered to be a usual and customary business practice; therefore the burden associated with the requirement will not be subject to the PRA in accordance with the implementing regulation of the PRA at 5 CFR 1320.3(b)(2).

Section 486.110 - Condition for coverage: Inspection of equipment.

(b) Standard—Records of inspection and scope of inspection. The supplier maintains records of current inspections which include the extent to which equipment and shielding are in compliance with the safety standards outlined in §486.108.486.110(b) -- Records of inspection and scope of inspection

.14 hour per supplier x 509 portable X-ray suppliers = 71 burden hours x $32 = $2,272

Total burden for portable X-ray suppliers is computed as:

486.104 - 255 hours
486.106 - 532,633 hours
486.110 - 71 hours
532,959 total burden hours

There are 532,959 total burden hours. The total cost estimate for all respondents is $26,928,788.

13. Capital Costs

There are no capital costs.

14. Cost to Federal Government

There is no cost to the Federal Government.

15. Changes to Burden

The changes to the burden hours are primarily due to public comments that CMS received. The comments, submitted by two entities during the public comment period for the CY 2018 SNF PPS proposed rule (82 FR 36530), stated that there is a conflict between the documentation required for portable X-ray orders and other diagnostic test as follows:

1. The regulations currently use obsolete terminology, which has caused confusion amongst providers and inconsistent implementation by the Medicare Administrative Contractors. In order to avoid misinterpretation, portable X-ray suppliers create duplicate orders to meet the exact specifications of the requirements at §486.106. This was not accounted for in the previous burden estimate.

2. The requirement that portable X-ray orders be “written and signed” creates an additional barrier to using efficient ordering methods such as telephone and electronic methods. Using paper-based ordering practices is time consuming and burdensome. This burden was not accounted for in the previous estimates.

Accounting for these new burdens increased the estimate by 532,055 hours and $26,908.588. Additionally, the salary estimate per burden hour increased by $15.10 in order to account for wage increases and to add in a 100% salary and benefits package.

Finally, the burden estimates were revised in order to reflect a decrease in the number of portable X-ray suppliers from 578 to 509.

16. Publication/Tabulation Dates

We do not plan to publish any of the information collected.

17. Expiration Date

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