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. There are currently 506 portable X-ray suppliers participating in the Medicare program (May 2021; https://qcor.cms.gov).

On November 19, 2008 (73 FR 69726), the Centers for Medicare & Medicaid Services (CMS) updated the requirements for portable X-ray technicians at 42 CFR 486.104(a) for qualifications, orientation and health of technical personnel, to reflect current requirements and community standards for personnel training. On November 16, 2012 (77 FR 68679) CMS revised the requirements at 42 CFR 486.106(a) and (b) to expand the scope of practitioners that could order portable X-ray services. This change expanded the requirement from physicians (MD & DO) to include other physicians and non-physician practitioners such as podiatrists, physician assistants, and nurse practitioners, among others. On September 30, 2019 (84 FR 51732), CMS again updated the personnel requirements for portable X-ray technicians at 42 CFR 486.104(a), to focus on the qualifications of the individual performing services removing school accreditation requirements and simplifying the structure of the requirements. Additionally, CMS also revised the requirements for referral of service at 42 CFR 486.106(a) for portable X-ray requirements for orders. This change removed the requirement that physician or non-physician practitioner's orders for portable X-ray services must be written and signed and replacing the specific requirements related to the content of each portable X-ray order with a cross-reference to the requirements at 42 CFR 410.32, which also apply to portable X-ray services.

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 portable X-ray 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 published on July 21, 2021 (86 FR 38485). There were

no public comment received.

The 30-day Federal Register notice published on October 5, 2021 (86 FR 54980).

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 2020 and includes an assumed 100% benefits and overhead package ($38 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.

Burden Estimate: 0.5 hour per supplier x 506 X-ray suppliers = 253 burden hours x $38/hour = $9614.

Section 486.106 - Condition for coverage: Preservation of records.

Section 486.106(c) 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 that 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.
Burden Estimate: 0.14 hour per supplier x 506 portable X-ray suppliers = 71 burden hours x $38 = $2,698.

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

486.104 - 253 hours
486.110 - 71 hours
324 total burden hours

There are 324 total burden hours. The total cost estimate for all respondents is $12,312.

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

During prior rulemaking for burden reduction initiatives (84 FR 51732), CMS revised the requirements for portable X-ray orders removing the requirement at 42 CFR 486.106(a) that orders for portable X-ray services be written and signed. Additionally, we also replaced the specific requirements related to the content of each portable X-ray order with a cross-reference to the payment requirements at 42 CFR 410.32, which also apply to portable X-ray services. These changes simplified the ordering process for portable X-rays and promotes the use of more efficient ordering methods, such as electronic orders resulting in a significant change of burden. This has resulted in a reduction of 532,633 burden hours and $27,650,289 (see 84 FR 51765).

16. Publication/Tabulation Dates

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

17. Expiration Date

CMS will update the forms with appropriate expiration date when approved.