Supporting Statement

Conditions for Coverage for

Portable X-ray Suppliers

(42 CFR 486 Subpart C)

CMS-R-43

0938-0338

A. BACKGROUND

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 for which we are seeking approval are contained in 42 CFR sections 486.104, 486.106 and 486.110.

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 experience; and
  (2) Employees receive adequate health supervision.

- 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 practitioners. 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.

(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.

o 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.

B. JUSTIFICATION

1. Need and Legal Basis

These requirements are among other requirements classified as (or known as) Conditions of Participation or Conditions for Coverage. These conditions are based on a provision specified in law relating to diagnostic X-ray tests "furnished in a place of residence used as the patient's home," and are designed to ensure that each supplier has properly trained staff to provide the appropriate type and level of care; as well as, a safe physical environment for patients. CMS uses these conditions to certify suppliers of portable X-ray services wishing to participate in the Medicare program. To examine these requirements, please see 42 CFR sections 486.104, 486.106 and 486.110. These requirements are required by 42 USC 1395m(c).

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 coverage 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

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

N/A. These are recordkeeping requirements.

7. Special Circumstances

There are no special circumstances for requiring this information.

8. Federal Register Notice and Outside Consultation

The 60-day Federal Register notice was published on XXX. There was no outside consultation.

9. Payment/Gift to Respondent

There will be no payment/gift to respondent.

10. Confidentiality

There are no assurances of confidentiality.

11. Sensitive Questions

There are no sensitive questions.

12. Burden Estimates

These requirements are self-imposed by the suppliers in accordance with good medical practice; however, it is possible that some burden would be eliminated or reduced in the absence of a CMS requirement. Therefore, for burden estimate purposes, we counted the portion of time we believe the suppliers expend on CMS requirements. The burden for this request is based on 578 portable X-ray suppliers.

486.104(c) -- *employee records

.5	hour per supplier
x 578	X-ray suppliers
289	burden hours

486.106(a)-(c) --*referral for service and preservation of records

1	hour per supplier
x 578	X-ray suppliers
578	burden hours

486.110(b) --*records of inspection

.14	hour per supplier
x 578	X-ray suppliers

81 burden hours

*These requirements deal only with keeping records that are already available. We believe that this is a minimal burden imposed on portable X-ray suppliers with these requirements. These requirements are comparable to industry standards and would be in place even in the absence of a Federal requirement. This estimate is, therefore, based on only the incremental burden for the portion of time we believe the suppliers expend on CMS requirements.

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

486.104 – 289.00 hours
486.106 – 578.00 hours
486.110 – 81 hours
948 total burden hours or (578 respondents * 1.64 total hours)

There are 948 total burden hours. The cost to collect this information is estimated at $16.90 per hour based on the average salary for an office administrative services staff person in 2012. The total cost estimate to the respondent is $16,021.20.

13. Cost Estimate to Respondent or Record keeper

There are no capital costs.

14. Cost to Federal Government

There is no cost to the Federal Government.

15. Program Changes

There are no program changes. The change to burden is due to a decrease in the number of respondents from 726 to 578. The burden hour decreased from 1815 to 948.

16. Publication and Tabulation Dates

There are no publication and tabulation dates.

17. Expiration Date

This does not lend itself to the displaying of an expiration date.