Request for Information on Radiation Safety and Occupational Protection in Fluoroscopy-Guided Interventional Procedures

SUMMARY: The Centers for Medicare & Medicaid Services (CMS) is issuing this request for information (RFI) to solicit public comment, data, and evidence on occupational radiation exposure and related musculoskeletal injury among clinicians who perform fluoroscopy-guided interventional procedures (including but not limited to interventional cardiology, interventional radiology, electrophysiology, and structural heart and peripheral vascular procedures), on the availability and performance of radiation-reduction and shielding technologies, on the clinical workforce and patient-access implications of unaddressed occupational hazards in this setting, and on the costs, benefits, and implementation considerations associated with expanded deployment of such technologies in Medicare- and Medicaid-participating facilities. CMS is issuing this RFI to inform its understanding of whether and how the existing Conditions of Participation (CoPs) governing radiologic services, and any related guidance, should be reexamined in light of technological developments since those requirements were last substantively revised. This RFI is issued solely for information-gathering purposes and does not itself propose, and should not be construed as proposing, any change to existing regulations, interpretive guidelines, or survey protocols. Responses to this RFI will not be publicly posted with individually attributed adjudications of accuracy but will inform CMS's assessment of whether further regulatory, sub-regulatory, or educational action is warranted.

I. Background

A. Statutory and Regulatory Framework

Section 1861(e) of the Social Security Act and implementing regulations at 42 CFR part 482 establish the Conditions of Participation (CoPs) that facilities must meet to participate in the Medicare and Medicaid programs. Among these, 42 CFR 482.26(b) provides, in relevant part, that "[t]he radiologic services, particularly ionizing radiology procedures, must be free from hazards for patients and personnel," and that "[p]roper safety precautions must be maintained against radiation hazards," including "adequate shielding for patients, personnel, and facilities." The regulation further requires periodic inspection of equipment and correction of identified hazards, and periodic monitoring of radiation workers' exposure through dosimetry.

The substantive text of § 482.26(b) has remained largely unchanged since the CoPs were last comprehensively revised in the 1980s. In the intervening decades, the volume, complexity, and intensity of interventional procedures performed in cardiac catheterization laboratories, electrophysiology suites, and interventional radiology suites have increased substantially, as has the published clinical literature characterizing occupational radiation exposure and orthopedic burden among the physicians, nurses, and technologists who perform these procedures.

CMS is aware that the United States' current annual occupational radiation dose limit for adult workers (50 mSv) differs from the 20 mSv annual limit recommended by the International Commission on Radiological Protection and adopted by other nations. CMS is also aware that stakeholders contend this difference results in U.S. interventional operators being exposed to

higher occupational doses than their counterparts in jurisdictions applying stricter annual limits. CMS solicits data substantiating or qualifying these comparative claims.

B. Reported Occupational Hazards in Interventional Fluoroscopy

CMS has reviewed and is aware of published literature, survey data, and stakeholder submissions describing two related occupational hazards associated with fluoroscopy-guided interventional procedures:

1. Ionizing radiation exposure. Multiple published sources report that operators in interventional cardiology and related specialties receive materially higher scatter radiation doses than personnel in diagnostic radiology and describe case series of malignancies – including brain tumors with a reported left-lateralization pattern consistent with typical operator positioning – in interventional operators. Peer-reviewed data has also reported an elevated relative risk of posterior lens opacity among interventional cardiology staff relative to unexposed controls, with a reported dose-response relationship. Additional research indicates an association between radiation exposure and reproductive harm, as well as inflammatory, vascular, and immune system damage. CMS solicits comment identifying the most methodologically rigorous available epidemiological data on ionizing radiation exposure.

2. Musculoskeletal injury associated with protective garments. Standard lead aprons and thyroid shields used to protect operators from radiation can weigh as much as 20 pounds and are worn for extended periods during procedures. A survey of cardiac catheterization laboratory personnel by a national interventional cardiology specialty society reported that a substantial majority of long-tenured respondents had experienced work-related orthopedic symptoms, that a meaningful minority had curtailed clinical workload because of injury, and that cervical and lumbar spine injury prevalence among respondents exceeded general-population baseline rates. CMS solicits facility-level occupational injury or workers' compensation claims data that may provide precise quantification on musculoskeletal injury associated with protective garments.

C. Available and Emerging Radiation-Reduction and Shielding Technologies

CMS understands that several categories of technology are currently being deployed to reduce operator radiation exposure and the physical burden of protective garments, including: (1) imaging-system software and hardware intended to reduce radiation dose while preserving diagnostic image quality; (2) suspended, floor-mounted, or patient-mounted shielding systems intended to reduce operator scatter exposure without requiring the operator to bear the shield's weight; (3) real-time, wearable or room-based dosimetry systems intended to provide operators with exposure feedback; (4) lead-reduced or lead-free garments using alternative attenuating materials intended to provide comparable protection at reduced weight; and (5) sterile, disposable, lead-free shields and drapes that block radiation emanating from the patient during an interventional procedure.

CMS is aware of published and industry-sponsored performance data reporting substantial reduction of up to 90 percent in measured operator dose associated with certain shielding configurations relative to lead-apron-only baselines. CMS understands at least one prospective,

multicenter randomized trial of a shielding technology is registered and enrolling as of this notice. CMS solicits comment on the documented utility of radiation-reducing and shielding technologies in reducing disease, injury, or death among operators, with such documentation to include peer-reviewed or otherwise controlled studies wherever possible.

D. Reported Workforce, Access, and Financial Considerations

Stakeholders have submitted or published information asserting that: (1) the interventional cardiology training pipeline is structurally limited relative to projected workforce need; (2) premature departure of interventional clinicians due to occupational illness or injury imposes direct replacement, recruitment, and revenue losses on hospitals; (3) rural and other medically underserved areas face disproportionate cardiovascular access constraints that may be compounded by clinician attrition; and (4) the capital and operating costs of deploying advanced radiation-protection technology in a given laboratory may be substantially lower over a multi-year horizon than the estimated cost of preventable clinician departures. CMS solicits comment providing verifiable, facility-level, or claims-based data on workforce attrition, recruitment cost, hospital closure, and rural access outcomes attributable, in whole or in part, to occupational radiation or musculoskeletal hazards in interventional fluoroscopy.

II. Purpose of This Request for Information

CMS is issuing this RFI to gather information that will assist the agency in evaluating: (1) whether the existing CoPs at 42 CFR 482.26(b) and associated interpretive guidance adequately address occupational radiation and musculoskeletal hazards in light of current interventional practice and available protective technology; (2) whether additional CMS action – regulatory, sub-regulatory, or educational – is warranted, and if so, what form such action should take; and (3) the costs, benefits, feasibility, and unintended consequences that may be associated with various potential approaches. This RFI does not constitute, and should not be interpreted as, a proposed rule, and CMS is not at this time proposing any amendment to 42 CFR 482.26(b) or to the applicable interpretive guidelines.

III. Solicitation of Public Comment

CMS invites public comment on the following and encourages commenters to provide underlying data, citations to peer-reviewed literature, and facility-level or claims-based evidence wherever possible:

Occupational Hazard and Epidemiology

1. What peer-reviewed epidemiological data exist quantifying the incidence of radiation-attributable malignancy, cataract, reproductive harm, or cognitive effects among U.S. hospital-based interventional fluoroscopy personnel, disaggregated by role (physician, nurse, technologist) where available?
2. What data exist on musculoskeletal injury incidence, severity, and career impact among cath lab and interventional radiology personnel, including workers' compensation claims data?

3. To what extent do current occupational dosimetry monitoring practices in U.S. hospitals capture cumulative operator exposure accurately, and what gaps, if any, exist in current monitoring and reporting requirements under § 482.26(b)(1) through (3)?

Technology Performance and Adoption

4. What controlled or randomized clinical evidence exists evaluating the efficacy of dose-reduction software/hardware, shielding systems, real-time dosimetry, and lead-alternative garments, individually or in combination?
5. What is the current rate of adoption of advanced radiation-protection technologies across U.S. interventional laboratories, and what real or perceived factors (cost, reimbursement, facility infrastructure, awareness, clinician preference) most influence adoption or non-adoption?
6. Are there safety, workflow, ergonomic, or infection-control tradeoffs associated with these technologies that should inform any potential regulatory approach?

Cost, Financing, and Facility Impact

7. What verifiable data exist on the capital and operating cost of deploying advanced radiation-protection technology in an interventional laboratory, and how do these costs vary by facility type, geography, and configuration?
8. What verifiable data exist on the direct and indirect costs facilities incur when an interventional clinician is unable to practice, temporarily or permanently, due to occupational illness or injury?
9. Are there current reimbursement, capital financing, or cost-reporting barriers that impede facility investment in these technologies, and would any specific CMS action (e.g., clarification of allowable cost treatment) meaningfully affect adoption?
10. What is the anticipated differential impact, if any, of expanded deployment requirements on rural, critical access, and other resource-constrained hospitals, relative to larger or urban facilities?

Workforce and Access

11. What data exist linking occupational radiation or musculoskeletal hazards to clinician attrition, early retirement, or specialty choice, including among women and other groups that may be differentially affected?
12. What data exist on the relationship between interventional cardiology or interventional radiology workforce availability and measures of patient access, including procedural wait times and geographic access, particularly in rural and medically underserved areas?

Regulatory Approach

13. Should CMS consider revising the interpretive guidelines associated with 42 CFR 482.26(b) to more specifically address radiation-shielding technology, occupational radiation annual dose limits, ergonomic/orthopedic protection, or dosimetry practice, and if so, what specific revisions would commenters recommend?
14. Should any such revision specify particular technology categories or performance benchmarks, or should it remain performance-based (i.e., requiring facilities to demonstrate hazard mitigation without specifying particular technologies)?

15. What role, if any, should national accrediting organizations (e.g., deemed-status accrediting bodies) play in assessing compliance with any revised radiation-safety expectations?
16. Are there existing federal or state radiation-safety requirements (e.g., NRC, Agreement State, OSHA) that would overlap with, duplicate, or conflict with any CMS action in this area, and how should CMS coordinate with those authorities?
17. What unintended consequences – cost, access, workflow, or otherwise – should CMS consider before pursuing any regulatory or sub-regulatory change in this area?

General

18. Are there other data, studies, or considerations not addressed above that CMS should take into account in evaluating this issue?

IV. Response to Comments

Because of the large number of public comments CMS normally receives on Federal Register documents, CMS is not able to acknowledge or respond individually to comments received. CMS will consider all comments received by the date and time specified in the DATES section of this notice, and, if CMS proceeds with further action, CMS will respond to comments in the preamble to any subsequent rulemaking, as required by law.

V. Collection of Information Requirements

This document does not impose any new or revised "collection of information" requirements or burden as defined under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.). Consequently, it need not be reviewed by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995. Public participation in this RFI is voluntary.

VI. Regulatory Impact Statement

This RFI does not itself have an economic impact, as it does not establish any new requirement or burden. Any regulatory impact analysis will be conducted, as applicable, in connection with any subsequent proposed rule that may result from CMS's consideration of comments received in response to this RFI.