

The Federal Government's Oversight of CT Safety: Regulatory Possibilities¹

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Computed tomography (CT) has become a routine part of medicine in the United States, with close to 70 million scans completed per year (1). While the clinical benefits of CT have always come hand-in-hand with the risk of radiation exposure, it is not until recently that this risk has reached the forefront of public awareness, prompting the federal government to take a renewed interest in CT regulation (2,3). Two primary factors are responsible. First, in 2009 and 2010, reports were released describing nearly 400 patients who received radiation overdoses during perfusion CT imaging of the brain, resulting in hair loss and skin changes in some patients, and garnering widespread public attention (4,5). Second, unrelated to these events, investigators have projected that radiation-induced cancer risks from CT may be substantial at the population level (6,7). One analysis projected that up to 29 000 Americans may develop future cancers as a result of CT scans performed in 2007 (6). While these studies have known limitations—in particular, they do not account for competing risks relevant to ordering indications, and utilize extrapolated risk projections from atomic bomb survivors, many of whom received much higher doses—they nonetheless have elevated public concern and support the need for greater vigilance in CT practices (6,7).

The federal government has demonstrated an increasing willingness to intervene in health care in recent years, particularly when patient safety is believed to be at stake. In the case of CT safety, a federal regulatory response has already begun (5,8). To ensure that patients are maximally benefitted, the radiology community must become active participants in shaping regulatory efforts. While a working knowledge of the federal government's capabilities is impor-

tant for meaningful involvement, this body of knowledge is not at the fingertips of the practicing radiologist. In this report, we update the radiology community on the federal government's investigations of CT safety, deconstruct its authority and options for regulating CT practices, and examine current regulatory interventions as well as future possibilities.

Federal Inquiry into CT Safety

Until now, CT has been subject to relatively limited regulatory attention from the federal government. In fact, federal regulation of CT has been essentially restricted to Food and Drug Administration (FDA) clearance of CT scanners at the manufacturer level (2). There has been no significant federal oversight of hospital-based or nonhospital imaging facilities, nor have there been uniform national certification requirements for technologists operating CT scanners. This is in contrast to health care environments such as ambulatory surgical centers, clinical laboratories, home health organizations, and hospices, which have been subject to stringent federal accreditation requirements for years.

Existing regulatory efforts that apply to personnel and facilities performing CT have primarily been the product of state regulation and self regulation. The majority of states have regulatory schemes that address radiation control practices (9). These schemes vary in complexity and may include certification standards for radiologic technologists, scanner inspections, and other quality assurance measures (9–12). Nonuniformity in standards between states creates difficult to predict regulatory differentials along state lines, with up to six states not licensing or regulating radiologic technologists as late as 2011 (9–13). Within the radiology community,

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the American College of Radiology (ACR) has attempted to address quality concerns through voluntary accreditation programs in essentially all imaging modalities, including CT.

In the interest of identifying gaps within the current regulatory patchwork, the federal government welcomed radiologists, technologists, and industry experts from around the nation to discuss the issues surrounding CT safety. On February 26, 2010, the House Committee on Energy and Commerce convened a meeting of their Subcommittee on Health entitled “Medical Radiation: An Overview of the Issues” to hear testimony (14). Additionally, on March 30 and 31, 2010, the FDA convened a meeting of experts entitled “Device Improvements to Reduce Unnecessary Radiation Exposure from Medical Imaging” (15). While the testimony provided to Congress and the FDA was limited to a small number of experts and stakeholders, the discussion represented a preliminary framing of specific concerns surrounding CT safety, and included suggestions for possible reform. From the hundreds of pages of expert testimony and questioning produced by the hearings, three distinct contributors to the CT safety problem stood out: medical error, CT overutilization, and inconsistent dose optimization (14,15). Expert and stakeholder recommendations in each category are compiled in Figure 1. These expert recommendations may serve as a starting point for federal regulatory action.

Sources of Federal Regulatory Power

Even when the nature and scope of the CT safety problem is well defined, the federal government’s ability to intervene with a solution is limited by the scope of its Constitutional authority. Under the 10th Amendment, powers not enumerated to the federal government within the U.S. Constitution are reserved to the states. These reserved powers are collectively referred to as the state’s “police power” and generally include a state’s authority to promote the health, morals, safety, and general well-being of the community. Since the Constitution does

not explicitly enumerate a federal power to regulate health care, such authority has historically been reserved to the states according to the police power. As such, it has been the province of the individual states to license medical professionals and implement health care regulations, such as safety standards for CT imaging.

That being said, states are no longer lone regulators in the health care field. Over the past 50 years, the federal government has become increasingly influential in defining and regulating health care in the United States. This expansion of power comes from strategic leveraging of two of its seemingly unrelated constitutionally enumerated powers: the Commerce Clause Power and the Taxing and Spending Clause Power (16,17). Given that all federal authority in the health care field is essentially limited to these two powers, an understanding of the scope of these powers is fundamental for considering how the federal government might intervene to address the issue of CT safety.

Commerce Clause Power

Article I, Section 8, Clause 3 of the U.S. Constitution contains the Commerce Clause, which empowers the federal government to regulate commerce “among the several states.” In its most basic interpretation, the Commerce Clause gives the federal government authority to regulate the channels and products of interstate commerce. Since nationally marketed medications, medical devices, and diagnostic tests are all within the scope of interstate commerce, the federal government has broad authority to regulate these health care items through federal agencies, such as the FDA. However, in practical terms, the reach of the Commerce Clause Power does not end there.

A modern line of Supreme Court cases has substantially broadened the scope of federal authority granted by the Commerce Clause. In *Wickard v Filburn* (1942), the Court expanded the reach of the Commerce Clause Power to include the authority to regulate purely *intrastate* activity that could, in aggregate, have a substantial effect on inter-

state commerce (18). In 2005, the Court reaffirmed this principle in *Gonzalez v Raich*, with Justice Scalia explaining, “Congress may regulate even noneconomic local activity if that regulation is a necessary part of a more general regulation of interstate commerce” (19). This broader Constitutional interpretation provides the basis for an expanded federal role in health care by allowing the federal government to reach and regulate intrastate health care activities previously subject only to state regulation. Moreover, since the Supremacy Clause of the Constitution gives federal laws precedence over state laws, federally-based regulations cannot be undermined by conflicting state-based regulations.

An example of this expanded federal regulatory authority is the Mammography Quality Standards Act of 1992 (MQSA) (20). As the first major federal intervention in medical imaging, the MQSA established mandatory safety and quality standards for all facilities performing mammography. The Commerce Clause Power has also been used to implement mandatory quality standards for all of the clinical laboratories testing human specimens in the United States (21). To date, the constitutionality of these exercises of federal power has not been successfully challenged. However, clarification of the limits of the Commerce Clause Power, as it applies to health care, may be forthcoming as early as June 2012 when the Supreme Court decides the constitutionality of health care reform legislation passed under President Obama.

Taxing and Spending Clause Power

Compared with the Commerce Clause Power, the Taxing and Spending Clause

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Figure 1**MEDICAL ERROR****User Certification/Quality Assurance**

- Standardization of certification/education requirements for CT technologists
- Mandatory quality assurance processes

Adverse Event Reporting

- Improved mechanisms for technologists and staff to report medical errors within institutions
- Improved reporting of adverse events to the FDA
- Provide better access to the adverse event database at the FDA

CT Scanner Design

- Warning or lock-out systems to prevent radiation overdoses, restricted log-in access to scanners, restricted access for changing CT protocols
- Standardization of CT terminology and protocol element names (eg, scout versus scanogram) to avoid user error
- Standardization of technical information provided to users

OVERUTILIZATION**Authorization Systems to Ensure Medical Appropriateness**

- Decision support systems for ordering clinicians
- Benefits management companies performing preauthorization assessments

Legislation to Limit Self-referral**DOSE OPTIMIZATION****Diagnostic Reference Levels**

- Diagnostic reference levels to distinguish between acceptable and inappropriate practices at the facility level

Dose-Reduction Techniques

- Improvement of current dose-reduction techniques and discovery of novel dose-reduction strategies
- Requirement for specific dose reduction features on forward production units (ie, tube current modulation, collimators)

Dose Tracking

- Documentation/reporting of radiation dose for every CT study
- National dose registry to help define best practices and allow for interfacility comparisons of dose indexes.

Figure 1: Specific expert recommendations from congressional and FDA testimony on ways to address the issue of CT safety. Recommendations were extracted from the House congressional hearing, "Medical Radiation: An Overview of the Issues," held in February 2010 and the FDA public meeting, "Device Improvements to Reduce Unnecessary Radiation Exposure from Medical Imaging," held in March 2010 (14,15).

Power has provided the federal government with a less direct but equally effective method for regulating within the health care field. Based on Article I, Section 8, Clause 1 of the Constitution, the Taxing and Spending Clause Power is defined by the federal government's right to spend federal tax revenues to promote general welfare. Like the spending power of any consumer, the federal spending power includes the right to set conditions on the receipt of payment.

As the largest consumer of health care in the United States, with Medicare spending making up over 20% of all medical expenditures, the federal government possesses a significant amount of buyer's leverage (22). Using this leverage, the federal government requires medical providers to meet federal regulatory mandates to receive payments from Medicare. While many of the mandates tied to Medicare reimbursement are intended to ensure high-quality

care for Medicare patients, some lack a clear nexus to Medicare patients and instead serve broader policy goals. For example, the Emergency Medical Treatment and Active Labor Act targets more generalized access-to-care issues by placing treatment obligations on hospitals participating in Medicare regardless of a patient's ability to pay (23).

Unlike direct regulation based on the Commerce Clause, health care regulations based on the Taxing and Spending Clause represent indirect regulation and are not mandatory. If a medical entity does not want to comply with these regulations, it can opt to relinquish the business of Medicare patients. Losing the business of Medicare patients, however, is not a viable option for most medical entities. As such, these regulations are compulsory, in effect, across most health care settings.

Prior federal health care regulations based on the Commerce Clause Power and the Taxing and Spending Clause Power provide valuable insight into how the federal government wields its limited authority to achieve health policy goals. Figure 2 identifies specific provisions within prior federal health care legislation with potential relevance to CT regulation (20,21,23–25).

Federal Regulatory Efforts to Date Relating to CT Safety

Working within its limited authority, the federal government has already taken steps that address the issue of CT safety. These steps include passage of the Medicare Improvements for Patients and Providers Act (MIPPA) in 2008 and heightened FDA oversight of CT scanners.

Medicare Improvements for Patients and Providers Act

As an exercise of federal spending power, provisions in MIPPA require nonhospital imaging facilities performing CT scans to meet comprehensive accreditation standards to participate in Medicare. The accreditation requirements effective January 1, 2012, include technologist and physician competence

certification, CT scanner performance standards, patient safety requirements, and quality assurance and quality control processes (26,27). In addition to these specific requirements, Centers for Medicare and Medicaid Services (CMS), the federal agency charged with implementing the accreditation process, was given seemingly unbounded authority to include “any other standards or procedures [it] determines appropriate” (26). Thus, additional accreditation requirements such as mandatory equipment features, structured reporting requirements, and patient consent obligations could be added as needed. The accreditation process will be carried out by three deemed status organizations, specifically the ACR, the Joint Commission, and the Intersocietal Accreditation Organization, which were selected by CMS based on criteria provided by Congress. To date, CMS has given these accrediting bodies considerable independence in fashioning accreditation standards and processes, resulting in heterogeneity across accreditation programs. However, CMS has also been known to take a very different posture whereby it dictates very specific requirements for what accreditation programs must include, and deemed status organizations must demonstrate that their accreditation programs meet or exceed those requirements. The accreditation of clinical diagnostic laboratories is one such example (28). As advanced imaging accreditation under MIPPA matures and unaddressed issues are identified, CMS may assert greater control over specific elements of the accreditation programs.

A significant limitation of the regulatory scheme under MIPPA is the exclusion of hospital-based imaging facilities from the accreditation requirements. The Consistency, Accuracy, Responsibility, and Excellence in Medical Imaging and Radiation Therapy (CARE) bill would address this shortcoming by extending federal education and certification standards for technologists to hospital-based imaging facilities as well (29). However, iterations of the bill have been stalled in Congress since 2005 and its eventual success is uncertain.

Figure 2

MAMMOGRAPHY QUALITY STANDARDS ACT (MQSA) (20,24)

Requires national licensure, accrediting, and reporting standards for mammography facilities

- Certification requirements for interpreting physicians, radiologic technologists, and medical physicists
- Equipment requirements including mandated imaging equipment features and prohibited equipment
- Medical record and mammography reporting requirements including mandated contents and terminology, required communication to patients and physicians, and mandatory record keeping
- Regular quality assurance reviews involving interpreting physicians, technologists, and equipment

CLINICAL LABORATORY IMPROVEMENT AMENDMENTS (CLIA) (21)

Regulates all laboratory testing performed on humans in the U.S., covering approximately 200,000 laboratory entities

- Established maximum daily workload limits for personnel examining cytology slides

EMERGENCY MEDICAL TREATMENT AND ACTIVE LABOR ACT (EMTALA) (23)

Requires hospitals participating in Medicare to provide care to any patient who presents to the emergency department suffering from an emergency medical condition regardless of the patient's insurance coverage or ability to pay.

HEALTH INSURANCE PORTABILITY AND ACCOUNTABILITY ACT (HIPAA) (25)

Requires the establishment of national standards for electronic health care transactions for providers

- Mandates the use of signed authorization regarding the release of confidential medical information

Figure 2: Specific provisions within federal health care legislation with potential relevance to CT regulation.

FDA Oversight of CT Imaging

In November 2010 the FDA, the federal agency that regulates drugs and medical devices marketed in the United States, published results and recommendations from its investigation of CT-related radiation overdoses (5). In this report and in a related white paper, the FDA explains that it will leverage its regulatory authority under the Federal Food, Drug, and Cosmetic Act in three major ways to improve CT safety (5,8). First, as the approval agency for medical devices, the FDA will drive adoption of new hardware and software safeguards meant to prevent unintentional overexposures. Whether this will be accomplished through new mandatory features of forward production CT units or through nonbinding guidance documents remains unclear. Second, as overseer of device

labeling, the FDA will require better organized and more comprehensive user information with a particular focus on quality assurance. Third, in its product surveillance role, the FDA reminded imaging facilities of their statutory duty to report adverse events associated with CT scanning, so that the FDA can address preventable risks.

Role of Expert Recommendations

As described above, federal expert testimony highlighted three focus areas in CT safety: medical error, CT overutilization, and inconsistent dose optimization (14,15). To date, federal interventions, as demonstrated by MIPPA facility accreditation and increased FDA oversight, have primarily addressed the problem of medical error. Conspicuously

absent from federal regulatory efforts have been steps targeting CT overutilization and inconsistent dose optimization. Here, we consider how the federal government could further leverage its regulatory authority to give effect to expert recommendations in these areas, as listed in Figure 1.

Overutilization

Overutilization of CT imaging results in innumerable patients being exposed to unnecessary radiation (30). Lehnert and Bree (31), for example, in a single-center retrospective study, found that 62% of head CT studies and 53% of spine CT studies were not appropriately ordered on the basis of evidence-based appropriateness criteria. Expert recommendations for addressing overutilization included authorization systems to ensure test appropriateness and legislative action to curb the problem of imaging self-referral.

Over the past two decades, health care plans have turned to preauthorization services provided by benefits management companies to ensure that imaging appropriateness criteria are met. However, in recent years, attention has shifted away from benefits management companies to computerized decision support systems. Preliminary studies have demonstrated that decision support systems can successfully reduce unnecessary imaging, translating into both health care savings and decreased radiation exposures (32,33). In light of these results, CMS has implemented a demonstration project to determine whether use of decision support systems can improve quality of care and reduce unnecessary radiation exposures for Medicare patients (34). Depending on the results, the federal government could tie use of decision support systems to Medicare reimbursements, resulting in widespread adoption of these systems.

Concerning the problem of self-referral, the General Accounting Office and multiple investigators have shown that physicians with financial interests in imaging centers order substantially more imaging studies than physicians without such interests (35–38). Congress recently took a small step toward

addressing the problem of self-referral in the Patient Protection and Affordable Care Act of 2010 (39). The Act amends the Federal Physician-Self Referral (“Stark”) Law by adding disclosure requirements for physicians providing in-office CT imaging (40). While disclosure requirements help mitigate inappropriate self referral, Congress could more definitively eliminate these harmful financial incentives by removing CT imaging from the in-office ancillary services exception list within the Stark Law.

The contribution of defensive medicine to overutilization continues to receive attention at the federal level (41). Studies demonstrate that physicians order more CT imaging than is medically necessary out of concern for malpractice liability, resulting in unnecessary exposure to radiation (42,43). Tort reform has been proposed as a means to curb overutilization; however, the evidence to support its effectiveness in this regard remains mixed (44,45). Further elucidation of this link could provide the additional political thrust necessary for passage of federal tort reform legislation.

Dose Optimization

Even when performing medically indicated CT scans, inconsistently applied dose reduction techniques result in further unnecessary exposures at both patient and population levels. Substantial variability in effective doses achieved (per scan type) across imaging sites has been reported (7,46). Expert recommendations for ensuring better, more uniformly practiced dose optimization include attention to diagnostic reference levels such as those published by the ACR, greater adoption of dose-reduction techniques, mandatory reporting of radiation doses so that exposures may be tracked, and widespread use of a national dose registry (47).

Diagnostic reference levels (DRLs) are based on the 75–80th percentile of surveyed doses from actual CT scans performed at representative imaging facilities (48). DRLs should not be used as hard regulatory limits, since appropriately performed radiologic studies

may exceed DRL values. Instead, DRLs are useful for quality assurance practices in which audits are performed to determine if a facility is regularly exceeding the reference level for a particular type of CT scan. In this way, DRLs can be used to identify facilities with poor dose optimization practices. Working within current federal regulatory schemes, two federal strategies could be used to assess facility compliance with diagnostic reference levels. First, CMS could mandate dose audits as a requirement for facility accreditation under MIPPA. Second, and less directly, the federal government could implement a pay-for-performance model, similar to the Physician Quality Reporting Initiative mandated by the Tax Relief and Health Care Act of 2006, in which imaging facilities would receive greater Medicare reimbursements if dose audits demonstrated compliance with specified DRLs (49).

Even if fully committed to the principle of dose optimization, an imaging facility remains limited by the dose reduction technologies available on its CT scanners. The FDA or CMS could encourage uniform availability of dose reduction technologies through FDA-mandated equipment requirements for device clearance on forward production units or through CMS-mandated equipment standards under MIPPA facility accreditation. Alternatively, the federal government could encourage CT equipment upgrades through tax incentives or subsidies.

To improve patient and population radiation dose tracking, the state of California recently passed Senate Bill 1237, which requires imaging facilities to report specific dose metrics, such as CT dose index volume and dose-length product, for every CT study (50). Similar reporting requirements could be added by CMS as a facility accreditation requirement under MIPPA.

Dose reporting requirements represent a key step in developing an effective national dose registry. Dose registries serve as an important reservoir of data, aiding quality improvement at the facility level and informing best practices on a national level. The ACR recently

launched a national dose index registry for CT in which facilities can voluntarily participate (51). Widespread participation is important for adequate sampling across all types of imaging facilities. CMS could encourage participation in dose registries through reimbursement incentives or even mandate participation by tying it to facility accreditation.

Avoiding Regulatory Pitfalls

Federal regulation of health care inherently threatens the federal-state balance of power by usurping what was historically a state function, and it comes with its own host of challenges. Accordingly, the federal government's Constitutional authority to regulate CT imaging should not serve as a priori justification for overriding existing state and self-regulatory mechanisms.

In the context of CT safety, five federal regulatory challenges merit specific mention. First, the costs of federal interventions could be considerable, depending on the specific mechanisms implemented. The magnitude of these costs must be explicitly considered alongside expected gains in patient safety to determine whether attendant expenditures represent a wise allocation of health care resources. Furthermore, payers and their capacities must also be considered in advance. Second, if regulatory compliance is enforced primarily through conditional Medicare reimbursements, and if compliance requires substantially increased operating costs (particularly if equipment upgrades are mandated), some practices might respond by turning away Medicare patients. This undesirable consequence could have downstream effects on access to care and service patterns that are difficult to predict. Third, if regulatory efforts are ill-informed, they could add unnecessary complexity to patient care thereby creating new sources of medical risk. Fourth, if federal regulatory schemes lack the versatility to accommodate changes in CT technology or medical practices in a timely manner or impose mandates that distort market incentives, continued innovation

in patient care could be stymied. Last, and of particular importance, regulatory efforts must not negatively affect medical practice at the patient level. Sufficient flexibility for patient-centered dosimetry must remain, enabling physicians to retain the authority to vary dose levels, as needed, based on the varied clinical settings at hand.

Concerns similar to these were voiced during consideration of MQSA in 1994. Nonetheless, studies and expert opinions demonstrate that the federal regulations enacted by MQSA have improved the quality of mammography without an appreciable effect on access (52–54). Discussing the success of MQSA before Congress, Dr. Steven Amis, past Chair of the Board of Chancellors of the ACR explained:

Much of the success of MQSA can be attributed to the fact that FDA did not attempt to recreate the wheel when establishing the standards it would adopt. Instead it built upon standards and processes that were already being successfully implemented on a voluntary basis within the profession. (14)

Notwithstanding the success of MQSA, federal action related to CT imaging is likely to provide an even greater regulatory challenge. The practice of CT imaging is comparatively multifaceted, spanning numerous organ systems and disease processes, and including both diagnostic and interventional applications. Given the challenges facing CT regulation, a strong partnership between regulatory bodies and the radiology community is essential. Fortunately, federal action to date gives promise to this partnership as demonstrated by the diverse expert panel convened by Congress, collaborative initiatives between the FDA and CT manufacturers, and selection of the ACR as one of the three deemed status organizations.

Conclusion

The federal government has the authority, precedents, and mechanisms to address CT safety concerns through comprehensive regulatory schemes. Federal

actions to date, namely imaging facility accreditation under MIPPA and increased FDA oversight, signify important steps aimed at eliminating the risk of accidental radiation overdoses. However, alone these measures only partially address the CT safety problem as defined by experts in Congressional testimony. Working together with states and the radiology community, the federal government could further leverage its authority to provide more comprehensive regulatory solutions that attend to overutilization and dose optimization. However, given that further federal intervention threatens the federal-state balance of power and has its own potential pitfalls, adequate justification for further federal action must exist.

In this report, we have provided a framework for understanding the federal government's regulatory authority and capabilities in the context of CT safety. Moving forward with this knowledge, it is critically important that the radiology community be equipped to engage in, or debate against, planned federal regulatory actions. In the end, whether achieved by federal, state, or self-regulatory mechanisms, any patient should be able to walk into any imaging center and be confident that his or her test will yield the most possible benefit, with the least possible harm. It is our responsibility to ensure that this singular goal is never put aside.

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