



Imaging Clinical Decision Support: The Time is Now

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EXECUTIVE SUMMARY

- Organizations need to be ready for the imaging workflow changes related to the legislative mandates of P.L. 113-93 (Protecting Access to Medicare Act of 2014). They also need to have a good understanding of what's required to meet these mandates.
- There has been only one large scale study to determine the possible value of imaging CDS. Beginning in 2009, CMS initiated the Medicare Imaging Demonstration (MID) project—its subsequent evaluation is very instructive.
- The use of imaging CDS will be required for submitting claims to CMS as of January 1, 2017. This means a mechanism that the Secretary of HHS has approved must be used and the results from that imaging CDS must be included on the claim submitted by the imaging facility.

A few academic centers and large healthcare enterprises have used imaging Clinical Decision Support (CDS) for years. However, soon imaging CDS will become common practice across the nation. It will be embedded in the workflow for the ordering providers to request advanced diagnostic imaging. See Box 1.

On April 1, 2014 the President of the United States signed into law the “Protecting Access to Medicare Act of 2014” passed by both houses of Congress. PL 113-93 mandates implementing evidence-based medicine by requiring ordering physicians to use imaging CDS for all Medicare enrollees for advanced (eg, high tech, such as MRI and PET) imaging to improve appropriate utilization and ordering of diagnostic imaging services and to reduce duplicate and unnecessary procedures and related costs. The legislation also directs the secretary of the US Department of Health and Human Services (HHS) to identify CDS tools or what HHS will establish as “mechanisms” (systems or software) that can help physicians and providers navigate the appropriateness imaging criteria. Furthermore, by November 2015 CMS (Medicare) must specify the final regulations for the implementation of

the law. The period for public comment for the proposed regulations is expected to begin early July 2015.

Although it took an act of Congress to make it happen, the new mandates are good for physicians, patients, and all healthcare stakeholders for several reasons including:

- Will provide physicians with the most appropriate procedures along with references from the medical evidence to foster a “learning organization.”
- Will allow physicians to determine the most “appropriate procedure” by utilizing the CDS recommendation or choosing something else for each patient, while avoiding the administrative burden of prior authorization; however, these choices will be tracked for accountability.
- Will ensure patients receive the most appropriate procedures for the best quality of care and standardization of care across all patients.
- Will move providers toward the value-based reimbursement elements of clinical and service quality as well as low cost.
- Will, most importantly, return radiologists to an active role in the diagnosis, treatment, and patient care continuum.

■ Box 1. CMS Regulations: Key Dates

- April 1, 2014—President Obama signed the “Protecting Access to Medicare Act of 2014”
- July 2015—Public comment period for the proposed regulations
- November 2015—CMS (Medicare) must specify final implementation regulations
- January 1, 2017—The use of imaging CDS required for submitting Medicare claims

For additional information about the new CMS regulations, go to www.cms.gov or www.federalregister.gov to review the proposed regulations once they are available for public comment.

Why Now?

From the initial emergence of managed care in the 1970s, to the Institute of Medicine’s report on deaths attributed to preventable medical errors in 1999, it has been long known that the US health-care system was lacking in evidence-based medical decision systems to help practitioners make the best diagnoses for their patients.^{1,2} Yet, the managed care approach created a layer of utilization review known as prior authorization that focused on externally controlling care decisions to keep costs low. For decades, physicians and radiologists alike were being managed instead of allowing or encouraging the ordering provider to know and use evidence-based medicine to manage patient care appropriately.

Some may argue that CDS is not proven nor needed. The counter argument is that CDS is not an invention of modern healthcare information technology—in fact, just the opposite is true. As far back as the 4th century BC, the ancient Greeks knew the importance of the science of medicine and, most specifically, standardizing medical decision-making.³ At the celebrated town of Epidaurus—considered the “birthplace of medicine”—six foot outdoor steles or carved stones prescribed algorithms the

Greeks used to guide medical diagnoses and treatment. Greeks would travel to Epidaurus to obtain the “best practices” that the Greeks knew at that time. Therefore, CDS preceded EHR by almost two millennia.

What is true, however, is that there has been only one large scale study to determine the possible value of imaging CDS. Beginning in 2009, CMS initiated the Medicare Imaging Demonstration (MID) project, which was evaluated by the Rand Corporation. The Rand results were reported to Congress and the public in a Final Evaluation in December 2014.⁴ Although the demonstration was far from conclusive, the evaluation of the MID is instructive for several reasons.

1. There were a few trends supporting the improvement of imaging ordering with CDS. For example, a small percentage of the clinicians did change their orders to the recommendation of the imaging CDS or did not order any imaging if no alternative was suggested. In addition, although not significant, Rand concluded that six of seven conveners [participating sites] achieved higher rates of appropriate ordering, while the seventh convener already had the highest rate of

- appropriate orders at baseline (82%). These increases in appropriateness are indicative of a successful intervention.
2. Compared to the brief review of the literature for imaging CDS, Rand also suggests that some MID findings confirmed elements from previous studies. For example:
 - a. The changes to ordering patterns were greatest for primary care physicians.
 - b. If an imaging procedure was selected by an ordering provider that was judged “low utility” or inappropriate, the orders were usually completed or performed anyway.
 - c. In general, some reductions to inappropriate ordering were made, but not in all instances.
3. Most disappointing and concerning, however, was the high percentage of orders where the providers could not find a guideline that applied. The Rand study referred to these instances as “Not rated.” This caused a paucity of data for analysis or, as the Rand study states, this “limited to one-third of our sample of DSS [CDS] orders (ie, rated orders) for many analyses.” More importantly, it suggests that either the users found it hard to determine which guideline to use or the clinical content was not broad enough to serve the diverse needs of all the users. Either of these explanations suggests that care needs to be taken to assure the imaging CDS is easy to use and has a broad and proven coverage of what will be needed by the ordering providers.

One other factor is also pushing the move toward imaging CDS now. It is common knowledge that US health-care costs are unsustainable, but what is new is the price sensitivity of patients at the point of care.⁵ For example, with a high-deductible health plan, consumers would typically have to cover virtually all advanced imaging procedures out-of-pocket compared to the PPO deductible where only ultrasound or x-rays would be out-of-pocket. This means that prices

are increasingly being compared by the patient in order to determine where to go. The healthcare market is dramatically changing when Walmart states, “Our goal is to be the number one healthcare provider in the industry.”⁶ With such changes, each healthcare organization will have to respond or face the consequences.

New Medicare Requirements

The use of imaging CDS will be required for submitting claims to CMS as of January 1, 2017. This means a mechanism that the Secretary of HHS has approved must be used and the results from that imaging CDS must be included on the claim submitted by the imaging facility (eg, hospital or free standing imaging center). The law applies to all outpatient advanced imaging Medicare claims, with explicit exceptions for emergency departments, inpatient, and for non-advanced imaging or in hardship situations.

The time is now. To be ready for the mandates, facilities need to get started immediately to be ready by January 1, 2017. The reason to get started now is it will take at least 2–3 months to implement once a mechanism has been selected. The mechanism selection process may take an organization 2–3 months to consider and then another 2–3 months to finalize the selection agreement. This could easily be a 9 month process. There is also the need to involve and communicate the new requirements to all ordering providers. Depending on the organization, it may also take weeks or months to involve all the parties and finalize the communication plan. Much less communicate to everyone needed.

The Mandates and Your Organization

Although the legislation might seem daunting, healthcare organizations and providers do not need to create their own systems—and, in the time available, it would be impossible to do so. Luckily,

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CMS will designate the mechanisms or companies that have developed CDS for imaging that can help providers meet the required legislative mandates and implementation. These imaging CDS companies are likely to be identified as mechanisms by end of 2015 or early 2016.

The expense to implement and use imaging CDS may be borne by any healthcare entity that benefits from the improved appropriateness of the imaging orders. However, the most logical source of payment to allow ordering providers to access and use imaging CDS would be from those who receive the financial benefit. That is, one would expect the imaging CDS expense to be the responsibility of either the risk bearer (payor or ACO), who may save money by reducing inappropriate use of imaging, or the performing provider (hospital, freestanding imaging center, and/or radiology practice), who needs these data to bill CMS for the imaging services. Several imaging CDS vendors offer straight transaction pricing (per order of service) and at least one offers subscription pricing tiers that can be cost effective and encourage greater use without greater expense. Other expenses for such items as implementation, electronic interoperability, and reporting may be additional expenses or included in the CDS pricing.

There are three important questions and several issues to consider when an organization evaluates imaging CDS mechanisms:

1. How helpful is the mechanism’s clinical content?
 - Look for a point of order system that empowers the physician or practitioner benefiting the peer-to-peer communication by allowing the radiology provider (or point of service provider) to see

the information and possibly add information to the order, including even changing the order (with communication to the ordering provider documented).

- Review the development of the Appropriateness Criteria process to make sure it is an objective process and will meet the needs for the ordering providers across the various medical specialties with regard to the literature and perspective of the subspecialties.
 - Evaluate the frequency of Appropriateness Criteria updates with access to medical literature for physician review and acceptance. This means the organization will be consuming the most current medical evidence for the best results.
2. How user friendly is the workflow?
 - Insist the user interface accommodates physician or other clinical staff making input to accommodate workflows in different office settings.
 - Check the ability of the mechanism or company to interface or integrate with the various EHR or RIS systems.
 - Choose a system or mechanism that allows clinical research or other local innovations to be compared to the standard medical evidence. This feature is important for organizations that may be developing cutting edge clinical literature or innovations not fully accepted as evidence-based medicine. Such clinical studies can assure compliance with special imaging protocols or clinical research. It will be important, however, to evaluate any algorithm that is not accepted as evidence to avoid increasing risk to the organization.

- Review the mechanism in light of the support for transition from ICD-9 to ICD-10 codes, as providers will also be making this transition shortly before the new imaging ordering process is required. The ICD-10 codes are more complicated and require more detail. The CDS mechanism may help with this or not.
3. Will the mechanism's imaging CDS assist in a value-based future?
- Require that information for potential outcome and practice-standard studies are available as part of the mechanism. Some mechanisms may charge extra fees either for providing the data that will be required for CMS reporting or for other advanced analytical tools. These services may be required or useful, but know what is included and what is a la carte.
 - Request access and connection to codes (both diagnoses and procedures), not only for standardization of care, but for cleaner and more efficient claims processing within the organization.
 - Consider the mechanism's approach to reducing practice variations for the patient, potentially even if the recommendation is for no imaging, an alternative non-imaging procedure, low-tech, or high-tech imaging. Also consider asking for any information about impact studies.
 - Evaluate what other features the mechanism has, such as safety information or radiation exposure, in order to meet multiple mandates from other entities such as the State or Joint Commission.
 - Examine expansion possibilities for the organization longer term. Although CMS requires using Appropriateness Criteria for advanced imaging for Medicare, many organizations can benefit from implementing for all diagnostic imaging for value-based reimbursement. Consider if the imaging CDS approach could

benefit the inpatient, emergency department, and other payers for a more comprehensive, system-wide implementation of imaging CDS. It's only a matter of time before imaging CDS for all patients is required or desirable.

Conclusion

The requirements in P.L. 113-93 might seem overwhelming for some organizations and providers, yet taking control of medical decision-making and putting it back in the hands of healthcare providers is needed to improve efficiency, quality, and manage costs. It might require 21st century tools and technologies, but it is a philosophy and practice that even the ancient Greeks knew was at the heart of the science of medicine and good patient care. ☸

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