

<p><b>Brigham and Women’s Hospital</b></p> <p><b>Elizabeth G. Nabel, M.D.</b>, President</p> <p><b>Allen L. Smith, M.D., MS</b>, President, Brigham and Women’s Physicians Organization, Inc.</p> <p><b>Steven E. Seltzer, M.D.</b>, Chair, Radiology</p> <p><b>Ramin Khorasani, M.D., MPH</b>, Vice Chair, Radiology</p>	<p><b>New York-Presbyterian Hospital-Weill Cornell Medical Center</b></p> <p><b>Robert E. Kelly, M.D.</b>, President, New York-Presbyterian Hospital</p> <p><b>Robert Min, M.D., MBA</b>, Chair, Radiology</p> <p><b>Keith Hentel, M.D.,MS</b>, Exec. Vice Chair, Radiology</p>
<p><b>University of California Health System</b></p> <p><b>Ronald Arenson, M.D.</b>, Chair, Radiology and Biomedical Imaging, UC San Francisco</p> <p><b>Dieter Enzmann, M.D.</b>, Chair, Department of Radiologic Sciences, UC Los Angeles</p>	<p><b>Geisinger Health Systems</b></p> <p><b>Glenn Steele, M.D., Ph.D.</b>, President</p> <p><b>John Cardella, M.D.</b>, Chair, Radiology</p> <p><b>Jonathan Darer MD, MPH</b>, Chief Innovation Officer</p>

February 13, 2015

COVER SHEET

TO PAMA RECOMMENDATION LETTER TO CMS

The attached letter sets forth recommendations to the staff of the Centers for Medicare and Medicaid Services regarding a national strategy and approach for implementing the Protection Access to Medicare Act of 2014 (PAMA), and reflects the belief of the signatories that PAMA can be implemented in a fashion that:

- Promotes continuing improvements to the quality of care delivered to Medicare beneficiaries,
- Respects and facilitates the use by providers of local best practices in learning systems, and
- Reflects the disparate resources available to providers and the varied circumstances in which healthcare services are delivered in the United States.

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February 13, 2015

Joseph Dolph Hutter, MD, MA  
 LCDR, US Public Health Service  
 CMS Center for Clinical Standards and Quality  
 7500 Security Blvd  
 Baltimore MD 21244

Re: Protecting Access to Medicare Act of 2014 (42 USC 1395m);  
 Recommendations for implementation

Dear Dr. Hutter,

The signatories of this letter hereby respectfully offer their opinions and recommendations to the staff of the Centers for Medicare and Medicaid Services regarding a national strategy and approach for implementing the Protection Access to Medicare Act of 2014 (PAMA).

**Primary Recommendation**

The signatories recommend that CMS adopt a phased approach to implementing the requirements of PAMA by annually specifying a limited number of high quality appropriate use criteria (AUCs) for advanced diagnostic imaging services. More specifically, we suggest that CMS specify up to 10 AUC groups in the first year, and approximately 10 per year thereafter, to create a list of CMS Core AUC groups. Each AUC group would consist of one or more evidence-based guidelines associated with the same advanced diagnostic imaging service (ADIS) and specific clinical condition (SCC).

To do this, CMS would solicit the submission of proposed AUCs from qualified respondents. CMS would then select and specify AUCs by evaluating the proposed AUCs on the basis of the quality of the evidence underlying the AUC, the potential opportunity to improve the quality of clinical care

and the appropriate utilization of imaging<sup>1</sup>, the potential for applicability across a wide range of practices, whether the proposed AUC provides a framework for learning systems and future expansion, and such other factors as CMS may deem appropriate. The remainder of this letter describes our rationale and provides further information and suggestions for the implementation of this recommendation. (The full recommendation is presented beginning on page 10 of this letter.)

### **Qualifications of the signatories**

The signatories have substantial clinical, operational and research experience relating to the practice of medicine, the field of medical imaging and the domain of medical imaging information systems, including computerized physician order entry (CPOE) systems and clinical decision support (CDS) systems and the interface of such tools with enterprise wide electronic health records (EHRs).

### **Background**

Starting on January 1, 2017, PAMA requires healthcare providers to use approved CDS systems to consult approved appropriate use criteria when ordering certain advanced imaging procedures. PAMA defines the term appropriate use criteria (AUCs) as “criteria, only developed or endorsed by national professional medical specialty societies or other provider-led entities, to assist ordering professionals and furnishing professionals in making the most appropriate treatment decision for a specific clinical condition for an individual. To the extent feasible, such criteria shall be evidence-based.”

PAMA provides that the U.S. Secretary of Health and Human shall through rulemaking, and in consultation with physicians, practitioners, and other stakeholders, specify applicable appropriate use criteria for applicable imaging services only from among appropriate use criteria developed or endorsed by national professional medical specialty societies or other provider-led entities. In specifying applicable appropriate use criteria the Secretary of HHS is required to take into account whether the criteria have stakeholder consensus, are scientifically valid and evidence based and are based on studies that are published and reviewable by stakeholders. We have been informed that the Secretary has instructed the Centers for Medicare & Medicaid Services (CMS) to take steps to implement PAMA.

### **Guiding Principles for our recommendations**

The writers believe that the innovations contemplated by PAMA offer a rare opportunity both to improve the quality of medical imaging services delivered to Medicare beneficiaries and decrease the costs (waste) for such services. It is vital to note that implementing PAMA is not an information technology project; it is a national clinical performance improvement initiative with far reaching implications for patient safety, healthcare quality and costs. We believe that the AUC approach adopted by CMS for imaging will establish the minimum requirement for Promoting Evidence-Based Care; while many organizations (including those of the signatories to this letter) hope to implement evidence-based care programs that go well beyond this minimum, the minimum

required by CMS pursuant to PAMA should be achievable by large and small providers in all practice settings and environments in the United States.

Further, the successful implementation of imaging CDS under PAMA may serve as a model for extending this approach to performance improvement (improving quality and reducing waste) to other domains in healthcare, as alluded to in the final section of PAMA (which requires the Comptroller General of the United States to submit to Congress a report that includes a description of the extent to which AUCs could be used for other services, such as radiation therapy and clinical diagnostic laboratory services).

Against this background, this letter is intended to offer suggestions to CMS for complying with the requirements of PAMA in a manner that will be feasible given (i) the timetable required under the statute, and (ii) the practical realities and constraints applicable to the large and heterogeneous nature of the U.S. healthcare system. We believe that the optimal path for successfully implementing PAMA will:

- Result in the specification by CMS of AUCs that are formulated and made publicly available in a format that will facilitate rapid, relatively simple adoption by providers either through the provider's existing information technology systems or through other interoperable (with existing EHRs) information technology solutions available from many sources, or even through analog processes (such as telephone, web and paper workflows) for providers where this approach is necessary. This is particularly important for a national implementation of PAMA in light of the diverse environments and resources of providers across our country.
- Coordinate with existing processes (such as the CMS claims process), programs and resources to the extent practical, thereby minimizing duplication, costs and disruption;
- Reflect the lessons learned through real world experience with similar efforts, such as the Medicare Imaging Demonstration, published research, and local CDS implementations; and
- Enable and encourage nation-wide adoption of learning systems and performance improvement infrastructure for clinicians and health systems.

Under a separate PAMA requirement, not later than April 1, 2016 the Secretary shall publish a list of qualified decision support mechanisms to deliver the approved AUCs to ordering professionals. This letter does not directly address such mechanisms, although in keeping with the first guiding principle above we believe that the approved AUCs should be selected and designed to support an open architecture, interoperable (using existing IT integration standards) health IT environment so that they will not present a significant implementation barrier. We do suggest that the Secretary coordinate planning for the qualified decision support mechanisms with the certification process for electronic health records (EHRs) that already exists for the Federal Meaningful Use program that was created under the Health Information Technology for Economic and Clinical Health (HITECH) Act. We note that the current regulations defining 'meaningful use' already require the implementation of both CPOE and CDS technologies and we urge CMS to minimize duplicative or inconsistent requirements for providers to the extent practical under the requirements of PAMA.

## Lessons from the Medicare Imaging Demonstration

*Background:* Section 135b of the Medicare Improvements for Patients and Providers Act (MIPPA) of 2008 mandated an appropriate use of imaging services demonstration project. The Medicare Imaging Demonstration (MID), designed as an alternative to pre-authorization, thus assessed the impact of clinical decision support based on select professional society guidelines (with the great majority developed by the American College of Radiology and to a lesser extent by the American College of Cardiology) on 11 targeted high cost outpatient imaging procedures for Medicare fee-for-service patients. In the fall of 2010, CMS selected 5 conveners (Brigham and Women's Hospital, Henry Ford, Maine medical, National Imaging Associates, University of Wisconsin) to participate in the demonstration which began in October 2011. The RAND Corporation was selected by CMS to perform the pooled data analysis at the conclusion of the MID in October 2013. When ordering examinations (based on CPT code) covered under the MID, physicians were presented with clinical decision support drawn from the approved guidelines, which they could follow or ignore. Each order would be scored as appropriate, of uncertain appropriateness, inappropriate or not covered by guidelines. As required by the MIPPA, patients could have the exam ordered by their physician regardless of the outcome of the decision support interaction and although the ordering physician was required to document the reason for ignoring advice provided no immediate consequence of ordering imaging scored as inappropriate was enforced. Physicians did receive comparative data on their use and appropriateness of targeted high cost imaging compared to peers.

The Brigham and Women's Hospital (BWH) convenership enrolled over 10,000 providers in 4 health systems in 3 states (Brigham and Women's Hospital in Massachusetts; Geisinger Health System and the University of Pennsylvania Health System in Pennsylvania; Weill-Cornell Medical College in New York) and accounted for more than 75% of physicians enrolled in the MID.

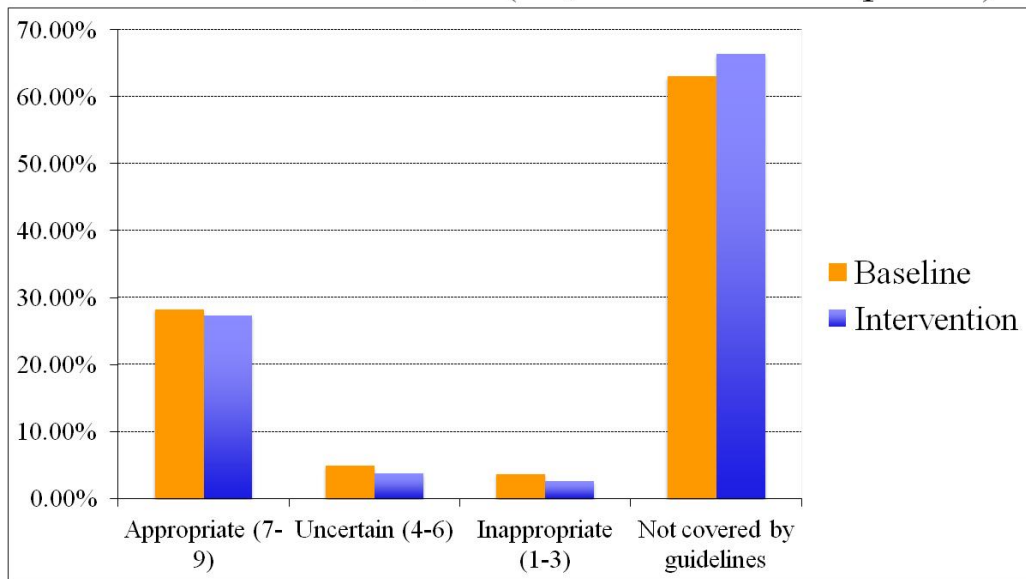
The multidisciplinary clinical leadership team of the BWH convenership (representing each participating health system) reviewed all the > 80 professional society guidelines selected by CMS for the MID. The selected guidelines were thus translated into >800 unique pieces of evidence which were then embedded in the clinical decision support tool used in the demonstration and integrated into each health system's electronic health record. In this process, the quality of each piece of evidence was scored and conflicts with local best practices at each health systems were identified. Due to Brigham and Women's Hospital's longstanding experience with imaging CDS prior to the MID including in domains where such local conflicts existed, the BWH data was excluded from the final report. Data from Geisinger Health System, University of Pennsylvania Health System and Weill-Cornell Medical College were included in the final results submitted to Congress.

The final analysis and results, prepared by Rand Corporation and subsumed in the final submitted to Congress by CMS in October 2014. For convenience, we have attached as **Appendix 1** to this letter a copy of the Medicare Imaging Demonstration Evaluation Report to Congress. This report describes the design of the MID, the approach used for appropriateness criteria, the problems encountered by the conveners and participants, and impact of the CDS intervention. The report summarizes important lessons of the MID that will assist CMS staff as they work to design an implementation strategy for PAMA. Our comments below are intended to supplement the MID report by providing our perspective on the lessons we have learned through the MID.

As stated in the MID report, the demonstration overall did not show a significant reduction in utilization of high cost imaging after implementation of professional society guidelines embedded in CDS. The slight reduction in the number of orders scored as inappropriate may simply represent additional clinical information entered by the ordering provider or their proxy in CDS (so that the order would no longer be deemed inappropriate) although the MID design did not include assessment of whether information entered into CDS was accurate and concordant with clinical information in the EHR.

The results for the BWH convenership (BWH, Geisinger, Cornell, Penn) are highlighted below. Of the >10,000 enrolled providers, > 4,000 entered at least one order for a procedure with a CPT code covered by the MID and were collectively exposed to > 83,000 CDS alerts in the 18 month intervention period. The overall summary results of the decision support for the baseline versus intervention period as well as the each health system in the BWH convenership are presented in Figures 1&2.

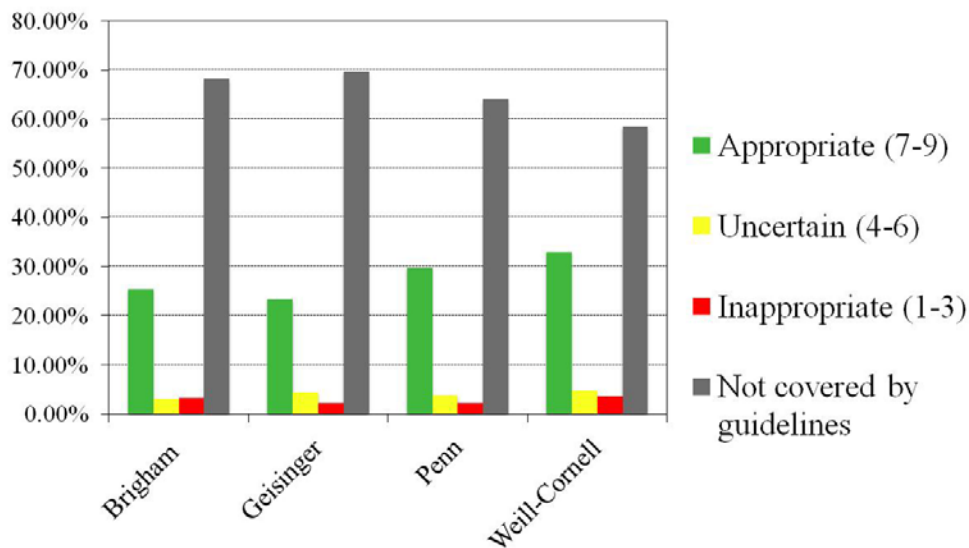
### Medicare Imaging Demonstration: BWH Convenship Total Orders: n=98,826 (15,762 in baseline period)



*Figure 1. 'Appropriateness' score of MID orders in the BWH convenership. Ordering providers were shielded from the appropriateness score in the control period but were exposed to the appropriateness score of their order according to applicable professional society guidelines, in the intervention period.*

## Medicare Imaging Demonstration: BWH Convenership

### Total Orders: n = 98,826



*Figure 2: 'Appropriateness' score for each of the health systems in the BWH convenership. A small portion of orders were scored as inappropriate or uncertain; these percentages were similar for each of the health systems. The apparent differences between rates of appropriate orders is balanced by the portion of orders without applicable guidelines, most likely reflecting differences in the ordering workflow among the four health systems.*

Most notably, when the clinical decision support was applied based on CPT codes, there were no guidelines that could be applied to >60% of the orders. Of the remaining orders nearly 30% were scored as appropriate, 5-6% scored as uncertain and 3-4% as inappropriate (Figure 1, 2). After the implementation of professional society guidelines embedded in CDS, we observed a slight reduction in the percentage of appropriate, inappropriate and uncertain orders with a concomitant increase in the percentage of orders without applicable guidelines. Again, given the lack of overall change in utilization of high cost imaging as reported by RAND, the changes we observed most likely represent ordering provider's 'clicking' behavior in CDS (such as clicking on more indications when placing an order resulting in the order not being covered by the guidelines) rather than any significant change in clinical decision making.

Ordering providers in the BWH convenership reported cancelling 26 MID orders in response to >83,000 CDS alerts in the intervention period (Figure 3). However, the order cancel rate could not be precisely measured, due to suboptimal integration between the electronic ordering systems and the clinical decision support systems in the timeframe provided by the MID. For example, ordering physicians had to manually cancel the original order, begin the ordering/decision support process again if an alternative order was to be placed, and report that they had done so as part of their attestation of exposure to CDS. The majority of the cancellations that were reported were in response to 'not covered by guidelines' alerts, which may reflect an erroneous perception among the ordering providers that the ordered service was not being covered by CMS (based on anecdotal feedback provided by a few ordering providers).

Medicare Imaging Demonstration: BWH Convenership  
 Total orders in the intervention period= n=83,064

Appropriateness Category	% Orders Cancelled	# orders cancelled
Appropriate (7-9)	0.00% (0/22656)	0
Uncertain (4-6)	0.06% (2/3168)	2
Inappropriate (1-3)	0.33% (7/2139)	7
Not covered by guidelines	0.03% (17/55101)	17

Figure 3. Number and proportion of MID orders cancelled in response to CDS alerts by appropriateness score

The MID results are in stark contrast to the published results of CDS-enabled interventions previous to and in parallel to MID. For example, prior to the MID, CDS had been utilized at BWH for >11 years delivering recommendations based on high quality evidence (as measured by Oxford ‘level of evidence’ or US preventative task force ‘grade of recommendation’) as part of multi-disciplinary targeted performance improvement initiatives to improve quality and reduce waste. For example, BWH has demonstrated:

- 30% reduction in the use of outpatient lumbar spine MRI on the day of PCP low back pain visit, a 12.3% reduction in the use of MRI within 30 days of index PCP low back pain visit, and an 18% absolute increase in adherence to American College of Physicians (ACP) guidelines for low back pain imaging (from 78% to 96%)<sup>2</sup>- a ‘Choosing Wisely’ campaign target from ACP.
- 13.4% reduction of head CT in the emergency department for minor head trauma<sup>3</sup> (American College of Emergency Physicians’ (ACEP) Choosing Wisely Campaign target).
- 20% reduction in the use of CT for suspected pulmonary embolism in the emergency department<sup>4</sup> (ACEP Choosing Wisely and NQF), as well as a 13% reduction for inpatients.<sup>5</sup>

These and other targeted CDS-enabled clinical interventions based on high quality evidence have impacted the use of high cost imaging more broadly at BWH. For example, BWH has demonstrated:

- 12% reduction in high cost imaging per 1000 member-months, sustainable over 4 years, for a commercial payer population.<sup>6</sup>
- 33% reduction in use of CT per 1000 emergency department visits.<sup>7</sup>
- 21% reduction in use of CT per 1000 inpatient admissions after adjusting for severity of disease.<sup>8</sup>
- 7.5% reduction in use of repeat CT in all care setting<sup>9,10</sup> (inpatient, outpatient, ED).



*Critical Insights From MID and other CDS implementations.* The contrast between the results of the MID and the results achieved with CDS prior to and in parallel to the MID within the BWH environment provide a direct comparison of alternative approaches to the implementation/use of CDS and provides insights that may help guide CMS staff as they plan the implementation of PAMA. These insights include:

1. An effective imaging CDS-enabled program is best viewed as a multi-disciplinary multi-specialty clinical program not an IT initiative. Stakeholder communication, engagement and buy-in relative to the evidence presented in the CDS are an essential component of successful programs. Healthcare delivery systems and providers will need time and focus to create the needed structures and processes to make implementation of imaging CDS clinically meaningful. An initial focus by CMS on a ‘few’ high quality AUC’s is thus critical to ensure long-term success.
2. Optimal integration of CDS into provider workflow (EHR where relevant) is important— ‘every click and scroll counts’<sup>11,12</sup>. As opposed to the successful integration of CDS and EHR at BWH, Penn, Geisinger, and Weill Cornell’s integration was achieved in the limited timeframe provided by the MID. This limited timeframe did not allow the respective EHR vendor adequate development time and therefore the integration was pieced together with then existing functionality and programming points. The consequence of such was a suboptimal integration in which several additional clicks to navigate through several different screens were required of the ordering physician. The resulting user dissatisfaction is well documented in the MID report to Congress.

To avoid these problems, CMS should take steps to minimize the technical barriers to the implementation of AUCs by EHRs and CDS vendors by promoting an open architecture, interoperable (using existing integration standards) health IT environment as envisioned with meaningful use regulations<sup>13</sup>.

3. The impact of evidence presented in CDS is NOT determined by the broadness of its ‘coverage’ rather by its clinical validity and its quality. As opposed to the targeted successful interventions achieved by BWH prior to the MID, the MID resulted in approximately 60% of all CDS alerts informing the ordering provider that ‘no guidelines were available’. This is a direct consequence of the fact that high quality evidence does not exist for specific imaging examinations (CPTs) but rather for specific clinical conditions (presentations/disease states). In fact, the broad application of CDS (attempting to cover CPTs rather than the specific clinical conditions for which high quality guidelines exist) as designed for the MID will result in low quality alerts (e.g., ‘not actionable’) without potential to improve care with alert/decision fatigue diminishing the impact of higher quality alerts.

It is thus important that CMS require AUCs for specific clinical conditions (presentations/disease states) and imaging procedures rather than for specific imaging procedures alone (CPT codes).

4. Evidence deployed through CDS will define a local standard of care. As part of the broad implementation of required guidelines in MID, each member of the BWH convenership was forced to implement guidelines 'as is' even when the guideline was in direct conflict with its own local best practices. MID guidelines embedded in CDS conflicted with local best practices of participating health systems (ranging from 5-30% as stated in the MID report, page 9). It would be unrealistic to assume that CDS can eliminate variation in practice broadly in the absence of national standards of care and heterogeneous medical practices including available imaging equipment, physician expertise, and patient populations.

CMS should enable provider-led entities the flexibility to review, adopt or adapt guidelines to reflect local best practices. The necessary structures (e.g. multi-disciplinary review expert panels) and processes (e.g. literature review, local considerations) will provide a framework to promote and accelerate the implementation of evidence-based care and associated performance improvement initiatives. All specified AUC's under PAMA, and their adaptations by provider-led entities should be made publicly available for clinical scrutiny to accelerate the creation of local adaptations if needed. Ultimately, a public domain, transparently and independently scored (the quality of guidelines/evidence created by any publisher should be externally validated as recommended by the Institute of Medicine<sup>14</sup>) repository of CDS consumable evidence from any source/publisher will accelerate national performance improvement initiatives to improve quality of imaging clinical programs and will help reduce waste. A project to create such a repository is now underway at Harvard Medical School (see <http://evidence.dev-solarisd.com/>)

5. The consequence of ignoring recommendations presented in CDS is a major predictor of its impact<sup>2,6,10,12,15</sup>. , MID did not include any significant consequence of ignoring CDS. In fact, providers could simply revert to using paper requisitions and refer imaging to other imaging providers, bypassing CDS entirely. CDS-enabled consequences may be either immediate (consultation needed prior to imaging) or longer term (e.g. penalties for physicians who are outliers in ordering practice). Once CDS has been broadly implemented, its impact will be optimized if CMS clearly defines and implements consequences for providers who consistently ignore high quality evidence. To make such measurements useful and clinically valid, ambiguous measures of appropriateness should be avoided<sup>12</sup>. Condition-specific measures of adherence to high quality evidence-based guidelines<sup>2,16,17</sup> are unambiguous and provide a useful framework for academic detailing and development /monitoring of clinical pathways to improve quality and reduce unwarranted variation and waste.

## **Recommendations:**

Based on the foregoing, the signatories respectfully recommend that CMS adopt a **phased approach** to implementing PAMA by soliciting the submission by **qualified respondents** (national professional medical specialty societies or other provider-led entities) of **proposed AUCs**. More specifically, we suggest that CMS specify up to 10 AUC groups in the first year, and approximately 10 per year thereafter, to create a list of CMS Core AUC groups. Each AUC group would consist of one or more evidence-based guidelines associated with the same advanced diagnostic imaging service (ADIS) and specific clinical condition (SCC). Each of these elements is further described in the paragraphs below, as well as our proposed process for the implementation.

**Process.** We propose that CMS issue its solicitation as soon as practicable, and require that proposed AUCs to be formulated by linking an evidence-based clinical guideline to a specific advanced diagnostic imaging service (ADIS) combined with a specific clinical condition (SCC). This formulation will allow CMS to group submissions into clinical categories (AUC groups), speeding the review process (which is vital to meet the PAMA deadlines). This formulation will ensure that when the AUC process is made operational by providers it will work relatively smoothly with the current CMS claims process (centered on CPT and ICD-10 codes).

Respondents would submit proposed AUCs by the deadline established by CMS in its solicitation. CMS staff would pre-process the submissions to confirm that the AUCs and the respondents who submitted AUCs meet the qualifications described below. Compliant AUCs would then be grouped into categories organized by CPT and ICD-10 codes, each associated with an evidence-based rule or guideline submitted by a qualified respondent. CMS would publish the full list of compliant AUCs (grouped as described) for public comment and would hold public meetings or other forums to meet PAMA's requirements for consultation with physicians, practitioners, and other stakeholders.

At the completion of the public consultation process, on or before November 15, 2015 CMS would specify a small number of high quality AUC groups selected from submitted proposals, taking into account such factors as the quality of the evidence underlying the AUC, the potential opportunity to improve the quality of clinical care and the appropriate utilization of imaging<sup>1</sup>, the potential for applicability across a wide range of practices, whether the proposed AUC provides a framework for learning systems and expansion, and such other factors as CMS may deem appropriate.

We note that the likelihood of successful adoption of a proposed AUC is directly linked to physicians' perception of the quality of the evidence presented in the AUC. This limited list of specified AUC groups might be termed the "**CMS Core AUCs**." Since more than one high quality, evidence-based guideline may be proposed for particular combination of a specific ADIS with an SCC, CMS may choose to specify the CMS Core AUCs as groupings of ADIS+SCC with associated evidence-based guidelines. We suggest that CMS set a goal of specifying up to ten CMS Core AUCs (or Core AUC groups) in November 2015, followed by an additional limited list in 2016, 2017 and subsequently. We also suggest that each AUC be subject to review/revision on a yearly basis (or

shorter if relevant, for example, if new substantial discoveries are made conflicting with the currently specified AUCs).

We recommend that the CMS Core AUCs be published in a format that will facilitate rapid, relatively simple adoption by providers either through the provider's existing information technology systems or through other interoperable (with existing EHRs) information technology solutions available from many sources. We further recommend that providers be permitted to implement the CMS Core AUCs as originally published by CMS or as set forth on a CMS approved list of operational formulations of the CMS Core AUCs (the "**Operational AUC List**"). The Operational AUC List would include the modified or adapted versions of the CMS Core AUCs submitted by any qualified national professional medical specialty society or provider-led entity. Such societies and entities would be authorized by CMS to modify or adapt the CMS Core AUCs (or AUCs already on the Operational AUC list) to make the AUC operational in the provider's environment and to comply with the providers' local best practices, so long as each such society or entity (i) demonstrates that it qualifies as a national society or provider-led entity, (ii) creates appropriate structures (such as multi-disciplinary expert review panels) and processes (such as reviews of literature and local considerations) for formulating local best practices, and (iii) provides its modified AUC to CMS for publication as part of CMS Operational AUC List. All AUCs included on the Operational AUC List would be made publicly available for clinical scrutiny and adoption by other providers promoting the concept of a national healthcare learning system.

**Phased Approach to PAMA Implementation.** As detailed in the discussion preceding our recommendation, the impact of evidence presented via CDS is not determined by the broadness of its 'coverage' but its clinical validity and its quality. Published research demonstrates that targeted, clinical performance improvement initiatives based on high quality evidence produce measurable and sustained improvements in quality together with reductions in waste. By contrast, the results of the Medicare Imaging Demonstration demonstrate that overly broad coverage based on extensive professional society guidelines results in a large number of low quality alerts leading to 'alert fatigue,' diminishing the impact of higher quality alerts, defeating the effort to improve quality or reduce costs.

By adopting a phased approach in which a small list of high quality CMS Core AUCs (or Core AUC groups) are selected in 2015, CMS will foster the maximum impact (improved quality and appropriateness of imaging) for the minimum disruption to clinical and operational systems. This approach will also improve the ability of providers and health systems to comply with PAMA requirements, and should allow a broad range of EHR and other health information systems vendors to provide the functionality that clinicians will need to comply with PAMA and to undertake large scale performance improvement initiatives to promote evidence-based care as envisioned under PAMA.

This approach would be conceptually similar to the phased approach employed to implement the policies envisioned under the HITECH Act to achieve specified improvements in care delivery through the 'meaningful use' of certified electronic health records (EHR). The recommended approach is also consistent with the imaging components of the 'Choosing Wisely' campaign

initiated by the American Board of Internal Medicine Foundation and with participation from many national professional societies. For example, the American College of Physicians (ACP), a provider led organization and national professional medical specialty society, has identified a short list of advanced diagnostic imaging services (linked to specific clinical conditions) for which high quality medical evidence regarding appropriate use exists. In compiling its list, ACP evaluated the scientific basis for the available evidence, secured stakeholder consensus, and has urged all U.S. physicians to refer to this evidence when ordering the listed imaging procedures.

**Qualified Respondents.** We recommend that the solicitation provide specific guidance regarding certain key terms used throughout PAMA, including the terms “**national professional medical specialty societies**” and “**provider-led entities**”. In formulating such definitions, we suggest that CMS take into consideration the size and makeup of each such group, while accommodating the differences between these categories. For example, to qualify as a national society, the group should be composed of a significant number (typically several thousand) of licensed providers from a single medical specialty, while a ‘provider-led entity’ may be comprised of far fewer providers from multiple medical specialties (perhaps as few as 50 providers encompassing two or more medical specialties to accommodate smaller groups or groups in rural settings). We further recommend that a qualified respondent describe the process used by respondent to develop or modify an AUC, such as the use of multi-disciplinary expert review panels, literature reviews, local data and practice reviews and similar elements relevant to the development and maintenance of local best practices. CMS would have the right to audit any such society or entity to confirm that such qualifications have been satisfied.

These definitions will have continuing importance if CMS adopts our recommendation that providers be permitted to modify or adapt the CMS Core AUCs to comply with the providers’ local best practices. The lessons of the MID (as described in CMS’ report to Congress) illustrate that local best practices sometimes conflict with AUCs as formulated by national societies and the same logic suggests that AUCs formulated by one provider-led entity may conflict with a different providers’ local best practices. By allowing provider-led entities to modify the CMS Core AUCs, CMS will allow providers to retain responsibility for delivering high quality care to patients as locally defined.

**Requirements for Proposed AUCs.** We recommend that the solicitation call for proposed AUCs to be formulated by linking a proposed clinical guideline to a specified advanced diagnostic imaging service (ADIS) combined with a Specific Clinical Condition (SCC). This formulation will allow CMS to group submissions into clinical categories, speeding the review process (which is vital to meet the PAMA deadlines). This formulation will ensure that when the AUC process is made operational by providers it will work relatively smoothly with the current claims process (centered on CPT and ICD-10 codes). Respondents would be instructed in the solicitation to (i) indicate the source and strength of the evidence underlying the proposed AUC, with the evidence scored using an objective scoring approach specified by CMS, such as the Oxford ‘level of evidence’ or US preventative task force ‘grade of recommendation’, (ii) employ brief, actionable, unambiguous language to express the AUC, and (iii) describe the potential for significant and positive impact on clinical care and appropriate imaging utilization if the proposed AUC is specified by CMS. This formulation of the proposed AUC with accompanying information would allow CMS and the physicians, practitioners

and other stakeholders consulted by CMS to sort the proposed AUCs into appropriate groupings based on specific clinical conditions and imaging modalities (ADIS and SCC), evaluate each proposed AUC consistently, and ultimately enable CMS to specify a list of high quality CMS Core AUCs groups that will be implemented under PAMA. An illustration of this approach is presented below.

**Operational Illustration.** To illustrate how our recommendation would be made operational, we provide the following example.

A qualified respondent submits a proposed AUC formulated as an evidence-based guideline for the use of MRI for lumbar spine for lower back pain (a specific clinical condition or “SCC”). If we assume that CMS selects and specifies this AUC as one of the CMS Core AUCs and that one or more PAMA compliant CDS mechanisms are approved for delivering the AUC, the proposed formulation would allow the AUC to be made operational in various clinical scenarios:

**Scenario 1:** Patient presents to primary care physician (PCP) complaining of lower back pain. PCP orders MRI of lumbar spine and states ‘lower back pain’ as reason for the order.

- CDS Mechanism results in application of an AUC
- Claim submitted to CMS shows an applicable diagnostic imaging service (CPT for MRI LS Spine) +/- SCC (depending on what ICD-10 is applied), which CDS Mechanism was used, which AUC was used (and this will imply the SCC), whether this diagnostic imaging service adheres to AUC, would not adhere to AUC, or whether the AUC became not applicable (based on additional information obtained during application of the AUC logic)

**Result of Scenario 1:** Complies with PAMA

**Scenario 2:** Patient presents to PCP complaining of injury to lower back. PCP orders MRI of lumbar spine and states ‘injury lower back’ as reason for the order.

- CDS Mechanism will NOT result in application of an AUC (assuming for this example that there is no AUC for the combination of MRI lumbar spine (CPT) and ‘injury lower back’ (ICD-10))
- Claim submitted to CMS shows imaging service (CPT for MRI LS Spine) +/- SCC (depending on what ICD-10 is applied), and no AUC applicable. The lack of the AUC will imply that the SCC was not one for which an AUC exists.

**Result of Scenario 2:** Complies with PAMA

**Scenario 3:** Patient presents to PCP complaining of lower back pain. PCP orders MRI of lumbar spine and states ‘lower back pain’ as reason for the order.

- CDS Mechanism results in application of an AUC
- Radiology interpretation shows a vertebral body fracture as a diagnosis (changes diagnosis—ICD-10)
- Claim submitted to CMS shows imaging service (CPT for MRI LS Spine) +/- SCC (changed ICD-10 due to diagnosis)), which CDS Mechanism was used, which AUC was used (implying the presenting SCC). In this scenario, while the AUC was applicable to the reason for the order (and therefore was applied to the order), it was not applicable to the diagnosis. Both data elements will be available to CMS and the local provider for learning systems purposes.

**Result of Scenario 3:** Complies with PAMA

**Analog Processes.** It is important to note that, although it would not be an optimal embodiment of the learning system, ordering providers could at least initially meet the ordering and claims requirements of PAMA in the above illustrations using a combination of telephone, web and paper processes, or even electronic ordering only for the required advanced diagnostic imaging services ADIS) whether or not the specific clinical condition and its applicable AUC is present. As a result, the implementation of PAMA will not supersede the requirements of the HITECH Act for the phase of CPOE for imaging as part of the ‘meaningful use’ regulations.

**Timeline.** To meet the deadlines included under PAMA, we suggest the following timeline:

March 15, 2015	CMS publishes a solicitation for submissions of proposed AUCs by qualified respondents
June 15, 2015	Due date for proposed AUCs
July 15, 2015	CMS publishes list of proposed AUCs for comment by physicians, practitioners and other constituencies
September 15, 2015	CMS convenes meetings with external experts
November 15, 2015	CMS publishes initial list of specified AUCs (CMS Core AUCs)

We greatly appreciate the opportunity to present our comments and recommendations. We are grateful for your efforts and the efforts of CMS' staff to find an optimal approach to the implementation of PAMA. If we can assist your staff by providing further information or answering questions, please do not hesitate to contact any or all of the signatories to this letter.

Respectfully submitted,



Steven. E. Seltzer, M.D., FACR  
Chair, Department of Radiology  
Brigham and Women's Hospital



Ramin Khorasani, M.D., MPH, FACR  
Vice Chair, Department of Radiology  
Distinguished Chair Medical Imaging Informatics  
Brigham and Women's Hospital



Elizabeth G. Nabel, M.D.  
President and Chief Executive Officer  
Brigham and Women's Hospital



Allen L. Smith, M.D., MS  
President  
Brigham and Women's Physicians Organization



Robert J. Min M.D., M.B.A.  
Chairman of Radiology  
Weill-Cornell Medical College



Keith Hentel, MD  
Executive Vice Chairman  
Department of Radiology New York Presbyterian Hospital,  
Weill Cornell Medical College

Robert E. Kelly, M.D.  
President  
New York-Presbyterian Hospital





John F. Cardella, M.D.  
Assoc. Chief Medical Officer  
Chairman—System Radiology  
Geisinger Health System



Jonathan Darer, M.D., MPH  
Chief Innovation Officer, Division of Clinical Innovation  
Clinical Director for the Clinical Decision Intelligence System  
Geisinger Health System



Glenn Steele, M.D., Ph.D.  
President and Chief Executive Officer  
Geisinger Health System



Ronald Arenson, M.D.  
Chairman of Radiology  
University of California, San Francisco



Dieter Enzmann, M.D.  
Chairman of Radiology  
University of California, Los Angeles

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## APPENDIX 1

### CMS REPORT TO CONGRESS ON MID

## Medicare Imaging Demonstration Evaluation Report to Congress

Section 135(b) of the Medicare Improvements for Patients and Providers Act of 2008 (P.L. 110-275) (MIPPA) required the Secretary of Health and Human Services to conduct a demonstration project in which data regarding physician compliance with appropriateness criteria are collected to determine the appropriateness of advanced diagnostic imaging services furnished to Medicare beneficiaries. Designed as an alternative to prior authorization, the Medicare Imaging Demonstration (MID) informed physicians about the appropriateness of their orders according to appropriateness criteria selected by the Secretary and programmed into computer order-entry systems known as decision support systems (DSSs).

The evaluation of MID sought to quantify rates of appropriate, uncertain, and inappropriate advanced diagnostic image ordering in the Medicare program and to determine whether exposing physicians to guidelines at the time of order is associated with more appropriate ordering and an attendant change in utilization. Under section 135(b)(5) of MIPPA, the Secretary is required to evaluate the demonstration project and to submit a report to Congress containing the results of the evaluation and recommendations for legislation and administrative action, as the Secretary determines appropriate, no later than one year after completion of the demonstration.

The two-year demonstration launched October 1, 2011 for physicians in one of five participating conveners across geographically and organizationally diverse practice settings. A convener was a single entity responsible for providing and supporting the use of a DSS for a collection of physician practices. Participation in the demonstration was voluntary, and there were no negative payment consequences for billed services for not consulting DSS. The statute required the Secretary to reimburse physicians for reasonable administrative costs incurred in participating in the demonstration project and to provide reasonable incentives to physicians to encourage participation. To meet this requirement, the conveners and physician practices received payment for their costs of participation when they supplied DSS records for the advanced diagnostic imaging procedures furnished during the demonstration. Physician practices decided how to distribute their payments to physicians. While physicians were required to consult the DSS every time they ordered an advanced diagnostic imaging procedure, they retained the autonomy to continue with or change their orders after consulting DSS, with no financial incentive to order more or fewer imaging procedures.

The statute described three different types of models for collecting data on appropriateness of orders—a point of service model; a point of order model; and any other model that the Secretary determines to be useful in evaluating the use of appropriateness criteria for advanced diagnostic imaging services. The demonstration tested the point of order model, as it reflected the state of the decision support market according to the environmental scan during the design phase of the demonstration. Any DSS could be used in the demonstration as long as it was programmed with the same appropriateness criteria used by all demonstration participants.

The contractor tasked with designing and operating the demonstration, the Lewin Group, identified the conditions and accompanying medical professional society guidelines associated with the 12 most common advanced diagnostic imaging procedures performed among Medicare beneficiaries—magnetic resonance imaging (MRI) of brain, knee, lumbar spine, or shoulder; computed tomography (CT) of abdomen, abdomen and pelvis, brain, lumbar spine, pelvis, sinus, or thorax; or Single Photon Emission Computed Tomography Myocardial Perfusion Imaging (SPECT MPI). When a physician—or a physician assistant or nurse practitioner who could legally order advanced diagnostic imaging—intended to order one of the 12 advanced diagnostic imaging procedures, he or she was required to consult a DSS programmed with the guidelines. The DSS, then, was intended to provide the ordering physician with instant feedback about the appropriateness of the order. If they entered a minimum of 30 rated orders over three- to six-month periods during the demonstration, physicians were also eligible to receive feedback reports about their appropriateness rates compared with the aggregated rates of their peers.

The data analyses and interpretation included in this report were prepared by the RAND Corporation (RAND) under contract with the Centers for Medicare & Medicaid Services (CMS). To perform its evaluation, RAND gathered information about the demonstration from the Lewin Group; analyzed DSS data and claims data; convened physician, staff, and patient focus groups that were supplemented with short questionnaires for physicians and staff; and conducted interviews with convener leadership. Most analyses were performed for each convener individually, rather than as a collective group, because the variety in structure of practices and DSSs fundamentally differentiated physicians' experience of the demonstration across conveners. To account for the impact of DSS on ordering behavior, 18 months of orders were analyzed relative to an initial 6-month baseline period of the demonstration during which orders were entered into DSS and rated without providing immediate appropriateness feedback to the

orderer. To account for existing trends in utilization of advanced diagnostic imaging, analyses of any changes in utilization involved a matched comparison group that did not use decision support for Medicare patients' advanced diagnostic imaging orders.

In its evaluation report to CMS, RAND directly addressed the impact and implications of the demonstration (Medicare Imaging Demonstration Evaluation Report, Appendix A). This Report to Congress summarizes RAND's findings, including factors required to be assessed or analyzed under section 135(b)(5) of MIPPA.

### Appropriate, Uncertain, and Inappropriate Ordering Rates and Patterns

In MID, advanced diagnostic imaging orders were entered into and rated by a DSS for appropriateness relative to four categories—"appropriate," "uncertain," "inappropriate," or "not covered by guidelines." "Appropriate" indicated that the order was consistent with the guidelines used in the demonstration. "Uncertain" meant that physicians should use their discretion because the guidelines for a given clinical scenario could not provide definitive guidance, while "inappropriate" signaled that the order was not consistent with guidelines. "Not covered by guidelines" displayed when the DSS order could not be linked to a guideline and, thus, could not be rated for appropriateness and was unrated in the demonstration. DSS orders could not be linked to a guideline when a physician's own reason for an order did not match the selected clinical indications in DSS used to link to a guideline or when a guideline simply does not exist for a given clinical scenario.

Over the course of the two-year demonstration, 3,916 physicians placed 139,757 initial orders for advanced diagnostic imaging procedures before receiving DSS feedback. Most physicians (70.5 percent of primary care physicians, 59.8 percent of medical specialists, and 64.6 percent of surgical specialists) placed fewer than 20 orders, or less than 1 order per month. A total of 8,345 orders (37.3 percent) during the baseline period and 40,536 orders (34.5 percent) during the intervention period could be rated for appropriateness (appropriate, uncertain, or inappropriate), resulting in a total of 48,881 (35.0 percent) rated orders that could be analyzed in both periods. The majority of orders could not be analyzed because they were "not covered by guidelines."

Among rated orders in the baseline period, between 61.5 percent and 81.8 percent were appropriate across conveners, representing the range of appropriate ordering rates in the fee-for-

service Medicare program prior to exposing physicians to appropriateness criteria through DSS. Likewise, between 10.3 percent and 21.0 percent of rated orders were uncertain at baseline across conveners and 7.8 percent to 18.1 percent were inappropriate. Compared with the baseline period, all but one convener showed an increase in the rate of appropriate ordering — with decreases in the rates of uncertain and inappropriate ordering—for final rated orders after physicians received DSS feedback on their orders in the intervention period. Conveners ranged from 75.1 percent to 83.9 percent in their rates of appropriate ordering during the intervention period, with rates of uncertain ordering between 11.1 percent to 16.1 percent and rates of inappropriate ordering between 5.3 percent to 9.0 percent. While the conveners overall seemed to show an improvement in appropriate ordering between the baseline and intervention periods, the percentage of unrated orders varied over time as well. Therefore, if the orders “not covered by guidelines” could have been rated, they may have changed the percentage of appropriate, uncertain, and inappropriate orders. For this reason, these changes in rates do not necessarily indicate an improvement in the appropriate ordering rate over the course of the demonstration.

When including both rated and unrated orders to determine the proportion of appropriate, uncertain, inappropriate, and unrated orders, most conveners sustained stable levels of appropriate and inappropriate rated orders between the baseline and intervention periods of the demonstration. The only convener that exhibited relative improvements in appropriateness rates between periods showed an accompanying decrease in the rates of unrated orders, perhaps indicating that ordering physicians learned how to use DSS more effectively over time because more of their orders could be linked to guidelines. Among rated orders during the intervention period, between about 2 and 10 percent of initially inappropriate orders were changed or canceled across conveners, with the exception of one convener, which had an 18 percent cancellation rate. Physicians with a high ordering volume of 50 or more advanced diagnostic imaging procedures over the course of the demonstration (about 2 procedures or more per month) might be expected to have higher rates of appropriate orders relative to those who ordered fewer procedures. Yet after analyzing thousands of orders in the low ordering volume group and high ordering volume group, changes in the rate of appropriately rated orders between the baseline and intervention periods were not more frequent for physicians with a high ordering volume at most conveners, indicating that greater use of DSS does not have a discernable effect on the likelihood of appropriately ordering advanced diagnostic imaging.



Since more than 60 percent of orders were unrated, examining the trends of rated orders alone does not account for the impact of the intervention on all orders. Therefore, the evaluation modeled the probability that the typical ordering physician at each convener would order an advanced diagnostic imaging procedure that would be unrated, inappropriate, uncertain, or appropriate. For conveners with an increase in the probability of an appropriate order between baseline and intervention periods, the probability of entering an unrated order still ranged from about 30 percent to above 80 percent. For conveners with a decrease in the probability of an appropriate order between baseline and intervention, there was a corresponding increase in the probability of an unrated order. Had only rated orders been analyzed for these conveners, the percentage of appropriate orders would have increased. Thus, the substantial share of unrated orders for each convener inhibits drawing definitive conclusions about the impact of exposing physicians to appropriateness guidelines through DSS on ordering advanced diagnostic imaging.

### Trends in Utilization

The evaluation examined trends in advanced diagnostic imaging utilization starting January 1, 2009—more than two years before the beginning of the demonstration—to November 30, 2013—two months after the close of the demonstration. Overall, the trends in advanced diagnostic imaging utilization did not noticeably differ for demonstration and comparison physicians before and during the demonstration, nor did they noticeably differ when stratified by convener or physician specialty type.

Propensity-weighted, difference-in-differences multivariate regression models were used to measure the physician-level effect at each convener of exposure to appropriateness guidelines through DSS during the intervention period relative to a comparison group and two separate preceding time periods—the approximately two-year pre-demonstration period and the 6-month baseline period at the start of the demonstration. In the model with the two-year pre-demonstration period, the estimated change in utilization was statistically significant for physicians within only two conveners, resulting in 1 to 2 fewer advanced diagnostic imaging procedures per 100 beneficiaries who had an office visit or any procedure at each of these conveners (or an average of 0.01 to 0.02 fewer advanced diagnostic imaging procedures per beneficiary). Only physicians within one convener had a statistically significant reduction in utilization of the same magnitude in the model with only the baseline period. Therefore,

exposing ordering physicians to appropriateness guidelines for advanced diagnostic imaging over the course of two years had no effect on utilization for physicians within most conveners, and where a statistically significant effect was found, its magnitude was very small and limited to two conveners at most.

### Appropriateness and Image Results

Because generating image results would have entailed a burdensome process of adjudicating results and forcing physicians to return to update their DSS orders days or weeks after an image was furnished, a direct analysis of the correlation between appropriateness of advanced diagnostic imaging orders and their results per se could not be performed. The DSS also did not capture the physician's own reason for an order in MID, which could be used to analyze whether the physician's reason for an order corresponds with the guideline triggered by DSS, if one were triggered. These data gaps are limitations of the demonstration. Instead, an analysis was undertaken of whether feedback about inappropriate orders during the first 90 days of the intervention period affected the utilization of advanced diagnostic imaging in the subsequent 90 days. It might be expected that physicians who placed a high volume of orders and had a relatively high proportion of inappropriately rated orders during their first exposure to DSS feedback would, in turn, have a reduction in utilization because they would learn not to order as many advanced diagnostic imaging procedures.

The analysis was limited to the 281 physicians with a minimum of 15 orders in the initial 90 days of the intervention period (i.e. at least 5 orders per month) and at least one order in the following 90 days. Since many orders could not be rated and only a small subset of rated orders were inappropriate, the evaluation was unable to definitively measure the impact on utilization. While the number of physicians in the analysis was relatively small, these results support the evaluation's findings that receiving feedback on inappropriate orders in the context of this demonstration did not result in reductions in advanced diagnostic imaging utilization.

### Physician and Patient Satisfaction

Physician and patient satisfaction during the demonstration was an implicit part of the performance standards in each convener's participation contract with CMS. If a problem with satisfaction threatened the demonstration's ability to be conducted, then the contractor operating

the demonstration responded quickly to remedy it or the convener ceased participation. No problems with physician satisfaction endangered conveners' participation contracts. Because the demonstration did not affect Medicare coverage or payment policy, beneficiaries were not notified if a physician ordered an advanced diagnostic imaging procedure while participating in MID. No known beneficiary complaints were filed in connection with MID.

The evaluation sought to understand physician and patient satisfaction with the demonstration through focus groups and short questionnaires. Convener leadership and physicians roundly liked the demonstration's intent to measure and improve the appropriateness of advanced diagnostic image ordering, but they found that MID's requirements for delivering guidelines through DSS was not an effective means to improve ordering behavior. In a supplemental questionnaire for focus group participants, more than half of physicians disagreed that the appropriateness guidelines delivered through the DSS used in the demonstration were informative or useful to their practice; were helpful in talking with patients about advanced diagnostic imaging; and allowed them to stay abreast of current best practices in advanced diagnostic imaging. Even so, generalists were more likely than specialists to have a favorable opinion of the guidelines.

Entering and changing orders in DSS added time to workflows. On average, physicians reported spending 3.9 minutes ordering an advanced diagnostic imaging procedure before the demonstration but 7.2 minutes during the demonstration. They might have been willing to spend more time ordering advanced diagnostic imaging if they thought the DSSs used in the demonstration added value to their workflows, yet physicians largely did not view them as such. The DSSs used in MID were designed to check the appropriateness of an advanced diagnostic imaging procedure that a physician planned to order. Physicians said that they would have preferred to receive guidance about different imaging procedures as they were considering placing an order, rather than deciding what to order and then consulting DSS. Spending time entering an order only to learn that it could not be linked to a guideline was especially frustrating for physicians. When an order was rated, the feedback itself simply provided a link to the guidelines, rather than providing tailored feedback to suit the context of a busy day of seeing patients. Physicians also felt frustrated from receiving DSS feedback based on guidelines that did not seem to account for all clinical aspects of the patient and sometimes conflicted with their local standards of care.

Physicians using the DSS in this demonstration perceived neither a positive nor negative effect on the quality of care their patients received. More than 80 percent of physicians believed that patients were not even aware when their orders were entered through DSS. They saw the potential of DSS to engage patients if patients insisted on receiving an advanced diagnostic imaging procedure that was inappropriate according to the guidelines, but physicians were not confident enough in the interface and guidelines themselves to use the DSS in this demonstration in that way.

Patients who received an advanced diagnostic imaging procedure ordered through DSS were aware that the order was placed through a computer but were unaware that the ordering physician received feedback on the appropriateness of the order. In fact, they generally seemed unknowledgeable that guidelines exist for ordering advanced diagnostic imaging procedures. Patients did not perceive any delays with ordering or scheduling during the demonstration.

## Lessons Learned

The demonstration was designed to provide ordering physicians with real-time feedback about the appropriateness of 12 of the most commonly ordered advanced diagnostic imaging procedures in the Medicare population. This design assumed that rigorous guidelines were available for the clinical scenarios leading to orders; that these guidelines could be programmed into the DSS in this demonstration in a user-friendly fashion; and that all physicians ordering these images would benefit from increased awareness of their appropriateness. However, convener leadership and physicians who participated in focus groups questioned whether these assumptions were valid.

A common set of national guidelines was used to rate the appropriateness of advanced diagnostic imaging orders. Because no independent consensus organization had developed appropriateness principles consistent with the statute requiring the demonstration, medical professional society guidelines were solely used as the standard to rate advanced diagnostic imaging orders for appropriateness. While professional societies might seem to be best informed to produce imaging guidelines, convener leaders pointed out that they exist to advance the interests of their members and thus have a vested interest in advising that imaging be ordered, particularly in instances where strong evidence underlying the guidelines is lacking. A limited number of advanced diagnostic imaging guidelines are supported by randomized control trials or

written based on clinical outcomes; many of them are based on expert opinion. Consequently, the guidelines are subject to differences in expert opinion and may not keep pace with local evidence that can fill gaps and lags in updating national guidelines. One convener estimated that 20 to 30 percent of the guidelines used in MID were in conflict with its own local standards of care. To participate in MID, conveners had to program guidelines into their DSS that were not necessarily consonant with their local standards of care. For ordering physicians, confusion might result when orders they expected would be appropriate according to local standards of care were rated uncertain or inappropriate.

Another source of confusion—as well as frustration—for ordering physicians were situations in which no guidelines exist. More than 60 percent of orders placed throughout MID could not be linked to a guideline, either because the ordering physician inadvertently did not enter the precise information into DSS to match to a guideline or because a guideline does not exist for a particular clinical scenario. As a result, physicians or their proxies would spend two to three minutes entering orders only to be informed that those orders were “not covered by guidelines.” Physicians stated that they found DSS to be a waste of their time when it indicated that their orders could not be rated. Specialists particularly found this type of feedback unhelpful because their expertise is limited to a set of advanced diagnostic imaging procedures that they order frequently.

DSS users’ frustration was compounded by the DSS interface with electronic medical records used during the demonstration, which varied in the extent to which both platforms were integrated—even across practices within the same convener. Without such integration, a patient’s clinical information had to be input separately into DSS, introducing the possibility that the requisite information to link to a guideline was not entered consistently. As a requirement of the demonstration, physicians had to attest to their orders—even for appropriate orders—which meant another click in the electronic ordering process. Another limitation of the demonstration occurred whenever ordering physicians were forced to close a DSS record and re-enter patient information to create a different order in response to DSS feedback or from radiologists after placing an order. Instead of enhancing workflows, the requirements for using DSS in the demonstration often slowed workflows and eroded physicians’ trust in advanced diagnostic imaging guidelines.

That many DSS orders could not be rated for appropriateness highlights the challenge of programming guidelines into an electronic user interface that can reliably trigger them. The clinical scenarios that lead a physician to consider ordering advanced diagnostic imaging represent numerous permutations of patient signs and symptoms that must be mapped to guidelines in DSS. These signs and symptoms—and their various exceptions—must first be captured in the guidelines. Assuming they are, they must be translated into computer code since the professional society guidelines used in MID were not originally written to be programmed into DSS, nor were they intended to provide real-time feedback to physicians about the appropriateness of their advanced diagnostic imaging orders. Finally, ordering physicians have to input the precise combination of clinical information into DSS to link to a guideline.

Conveners had to specially program the guidelines into the DSS used in the demonstration and implement it within a short time period of approximately nine months. The demonstration allowed each convener to procure its own DSS with the requirement that it be programmed with the common set of guidelines to MID. Conveners employed one of two main types of DSS designs. In one, users selected the patient characteristics and clinical indications for an order, which in turn were linked to a guideline variant to rate the appropriateness of the order. Another design was structured such that users clicked through a series of screens that asked questions about the indications for an order, which led to the appropriateness rating. This combination of flexibility in DSS design and rigidity in content meant that conveners could program the guidelines differently and users could arrive at different appropriateness ratings for the same clinical scenario depending on how they entered clinical information. That the percentage of orders “not covered by guidelines” varied more than three-fold across conveners is evidence that the DSSs and the way they were used were not uniform throughout the demonstration.

Even DSS users at the same convener did not necessarily have a uniform experience entering orders and receiving appropriateness ratings. Convener leadership reported difficulty in training physicians to use non-intuitive user interfaces that were not integrated into electronic medical records. A user might fail to trigger a guideline because the interface was not nuanced enough to incorporate more-detailed clinical information or the exact clinical indication, or constellation of indications, used to map to the guideline was not selected. Users might learn that entering a certain combination of indications always produced an appropriate rating and so they simply

entered what was needed to obtain an appropriate rating. Or, users might interpret the same appropriateness rating differently, leading to artificial variation in the number of changed orders.

According to convener leadership's informal feedback from physicians, the terminology used for each category in the appropriateness ratings was not plainly understandable nor provided meaningful information to ordering physicians. The appropriateness ratings were presented in a range from 1 to 9, where ratings 1 to 3 were "inappropriate;" 4 to 6 were "uncertain;" and 7 to 9 were "appropriate." The categories and their ranges reflect the way the guidelines were written, rather than based on the content and strength of the evidence supporting a linked guideline. Consider an imaging order with, for example, a rating of 6—in the "uncertain" range but close to being rated "appropriate." A physician might legitimately ask whether the order was rated "uncertain" because it might be inappropriate or appropriate depending on a patient's unique condition. Or was it "uncertain" because the evidence was ambiguous about advising one way or the other? Or did it indicate gaps in the evidence? Or was it really close to being "appropriate"? Although DSS feedback in the demonstration was linked to the guidelines triggering an appropriateness rating, users who wished to consult the guidelines themselves would usually have to search an electronic document with many pages for the guidelines of interest, rather than presenting the guidelines as a tailored summary explaining why an order was adjudicated a certain way. Few physicians in focus groups reported even consulting the guidelines.

In sum, while there are limitations of MID, it offers lessons that can be learned and suggests areas for improvement with integrating appropriateness criteria into tools designed to assist physicians with medical decision-making.

## Recommendations

The statute requires the Secretary to submit to Congress a report containing the results of the demonstration evaluation, together with recommendations for such legislation and administrative action, as the Secretary determines appropriate. RAND's report makes several suggestions for addressing the challenges noted with MID. Since this demonstration was completed, the Protecting Access to Medicare Act (P.L. 113-93) (PAMA) was enacted on April 1, 2014. Section 218(b) of such Act amended section 1834 of the Social Security Act (42 U.S.C. 1395m) by adding a new subsection (q), which established a program designed to promote the use of appropriate use criteria for applicable imaging services by ordering and furnishing professionals

in applicable settings. Ordering professionals would have to consult a qualifying decision support mechanism equipped with appropriate use criteria starting in 2017. Because the PAMA provision is just beginning to be implemented, there are no recommendations for legislation or administrative action. The evaluation of MID will be taken into account as the PAMA provision is implemented.