Questions Regarding the CMS Medicare Imaging Demonstration (July 2010)

The link to Frequently Asked Questions (FAQs) is:
http://www.cms.gov/DemoProjectsEvalRpts/downloads/MID_FAQs.pdf

[1] Could you clarify the difference between DSS support for Point of Order (POO) and Point of Service (POS)? What capabilities will the DSS require to support POS? Is it assumed that a participating provider can use the DSS to generate the equivalent of an order that can be delivered by hand (by the beneficiary) to the POS? Is it also assumed that such an 'order' must also be deliverable by fax or email from the DSS?

Both decision support systems must meet data collection and reporting requirements identified by CMS for purposes of this demonstration. The DSS must provide participating physician practices with (1) a means of entering requisite information, patient demographics, diagnoses and signs/ symptoms and, for some tests, additional clinical history; and (2) immediate feedback regarding the appropriateness of the order. The medical specialty society guidelines must be transparent to the physician practice such that the physician may understand how the appropriateness score is achieved.

The law described two models. The first is a Point-of-Order (POO) model that uses a computerized order entry system and requires inputting information at the time of referral and provides feedback about appropriateness of the order based on the input. For example, this could be a system that is embedded in an electronic health record or an electronic medical record or a DSS that is web-based.

The second model is called the Point of Service (POS) model. This model allows the physician practice that furnishes the imaging procedure the ability to participate in this demonstration without using a computerized order entry system, although the order must ultimately be submitted electronically to the convener for purposes of the demonstration. This arrangement permits systems that are less sophisticated to participate in the demonstration. The POS model, for example, may be where one physician practice both orders and furnishes the procedure. Another example may be most applicable to a radiology or cardiology practice, or to practices in rural settings, or for practices that telephone or fax the required demonstration information to the convener. Feedback regarding the appropriateness of the order is provided.

See FAQ Question #B.2

[2] What is the reason to require the same guideline criteria across conveners? Is there a need to compare conveners and the thought is there would be bias because of the guidelines if they were different? If the purpose of the demonstration project is to demonstrate the effect of a DSS that provides transparent access to guidelines, why can't a set of guidelines be used that closely reflect the official medical society guidelines, but which may provide more in-depth decision support. Or is the goal to demonstrate the effectiveness of that precise set of guidelines? Will CMS be selecting or evaluating the performance of different decision support systems in their impact on physician ordering behavior?

The statute requires that advanced diagnostic imaging services studied under the demonstration be evaluated against appropriateness criteria that satisfy two specific requirements outlined in the authorizing legislation. The goal of the demonstration is to collect data regarding the physician use of advanced diagnostic imaging services to determine the appropriateness of services in relation to established criteria and physician tiers. DSSs that that meet certain core requirements will be able to play a part in the demonstration, and we are not mandating physician participation. However, in order for CMS to collect meaningful data, we need some DSS standardization across demonstration participants.

See FAQ Question #B.3:

[3] Will test cases be made available prior to the Demonstration? If there is discordance with the outcome among conveners, what is the resolution process? Will there be an ombudsman to mediate differences? How will CMS deal with variations in how decision support systems assess appropriateness of services?

CMS will require conveners selected to participate in the demonstration to run test cases through their DSS prior to collecting physician practice data to validate that the DSS is in agreement with the specified guidelines. The results of the test cases will permit CMS to determine whether the conveners' implementation of medical specialty society guidelines is yielding sufficiently consistent appropriateness. Should the testing yield unacceptable results, CMS will work with the DSS developers and/or conveners to identify the problem and reach agreement with the medical specialty guidelines to be used under the demonstration.

[4] Will each convener have access to the results of all conveners as the test progresses? Can a convener perform its' own analysis and validate CMS conclusions?

No. While we hope conveners will perform their own internal validation processes, CMS will determine whether the conveners' implementation of medical specialty society guidelines is yielding sufficiently consistent appropriateness. We also expect conveners will work closely with CMS to ensure that the results of the tests are consistent with the medical specialty guidelines. Results will not be available to other conveners.

See FAQ #D.1

[5] How has the Hawthorne effect been factored into the assessment of the outcome of the demonstration? Isn't it the case that by asking for clinical data with respect to a particular test ordered the behavior of the participating physicians may significantly change? How will a valid baseline be set?

The pre-post research design will allow CMS to measure the impact of using a decision support system on the appropriateness of advanced diagnostic imaging services in the Medicare fee-for-service population. The baseline collection of data allows orders to be

rated by their appropriateness, which cannot be done with claims data alone. It is certainly possible that there may be an artificially lowered level of appropriateness because of a sentinel effect during the baseline collection of data. Some evidence of the extent of this effect will be obtained from advanced diagnostic imaging utilization of participating physicians during the previous year, as measured from claims data. In other words, the evaluation team will compare utilization during the baseline period with utilization during the same period of the previous year. If a sentinel effect is observed, the appropriateness rate estimate will be interpreted as a "lower bound" estimate.

See FAQ #A.9

[6] Can a DSS which is fully integrated into an electronic medical record (EMR) system be used? If that is the case then the EMR system may provide the relevant clinical data without querying the participating provider. How will comparisons be made between what would essentially be a system that alerts the provider to a potential inappropriate use of imaging to a system that requires data entry before such an assessment is given?

Yes, a fully EMR-integrated DSS can be used in the demonstration, provided that it meets the guideline criteria specified by the medical specialty guidelines. Physicians' experience with EMRs and DSSs will be incorporated into the evaluation of the demonstration.

See FAQ #A.5:

[7] Has consideration been made to include controls for fraud and abuse and "gaming" the system? For example, should a physician be allowed to re-enter data once a certain point has been reached?

CMS is aware that certain arrangements under this demonstration could raise possible fraud, waste, and abuse concerns, including concerns under the anti-kickback statute and the physician self-referral law. While CMS has the authority to waive the application of certain fraud, waste, and abuse laws, it is anticipated that doing so, if at all, will only occur after evaluating the provisions of the proposals on a case-by-case basis and considering whether waiver is necessary to carry out the demonstration project.

The goal of the demonstration is to collect data regarding the physician use of advanced diagnostic imaging services to determine the appropriateness of imaging services in relation to established criteria and physician tiers. Physicians will not be rewarded nor penalized based on the appropriateness of the imaging services actually ordered. The MID is not a pay for performance demonstration; therefore, there is no incentive for a physician to change data entered for purposes of "gaming."

See FAQs #E.1 and #E.2:

[8] How were the period selections (6/18 months) modeled mathematically to validate that these periods would be sufficient to provide statistically valid results across the entire range of imaging studies?

Power calculations were used to calculate the necessary number physicians and volume of ordered images to produce statistically valid results.

See FAQ #A.10

[9] Are there performance requirements for the DSS, for example time between screens?

No. The required technical specifications for a DSS are available at http://www.cms.gov/DemoProjectsEvalRpts/downloads/MID_DataSpec.pdf

[10] What standardization if any will be required in the functioning of the DSS? For example, should the data gathered in order to arrive at a particular decision on appropriateness be the same for all DSSs?

CMS will be testing whether each DSS is consistent with the appropriateness of ordering advanced imaging services using transparent medical specialty society guidelines with no pre-authorization requirement or changes to existing Medicare coverage or payment policies.

The required technical specifications for a DSS are available at http://www.cms.gov/DemoProjectsEvalRpts/downloads/MID_DataSpec.pdf

The medical specialty guidelines are available at http://www.cms.gov/DemoProjectsEvalRpts/downloads/MID_GuidelinesList.pdf

[11] How will the intellectual property rights of the DSS supplier be protected?

It is not the intent of the demonstration to test, compare, or endorse a specific DSS. There needs to be standardization of certain data elements across DSSs such as medical specialty guidelines, Medicare payment and coverage policies, and no prior authorization. While the intellectual property rights remain with the DSS vendor, the convener must agree to the terms and conditions for award by which CMS has access to proprietary systems to understand how they operate for purposes of implementation and evaluation of the demonstration.

[12] What role, if any, will third party advocacy groups play?

The Medicare Imaging Demonstration will test whether each DSS is consistent with the appropriateness of ordering advanced imaging services using transparent medical specialty society guidelines with no pre-authorization requirement or changes to existing Medicare coverage or payment policies.

[13] Is any other language but Standard English required to be supported by the DSS?

There are no language requirements (other than CSV for the data transmitted to and from CMS). However, we assume the DSS will be in a language that participating physicians are able to understand.

The required technical specifications for a DSS are available at http://www.cms.gov/DemoProjectsEvalRpts/downloads/MID_DataSpec.pdf

[14] Can FFS Medicare members opt out and refuse participation?

There is no demonstration enrollment for beneficiaries to opt in or opt out.

See FAQ #A.6:

[15] What, if any, are the requirements for retention of data generated during the demonstration? Does the data have to be retained after the demonstration is completed?

Conveners need to keep data long enough to ensure that CMS or the evaluator is able to access these data and to cover issues or questions arising over time. All data generated as part of the demonstration must be tendered to CMS by the completion of the demonstration's evaluation.