

Questions Regarding the CMS Medicare Imaging Demonstration (August 2010)

The link to Frequently Asked Questions (FAQs) is:

http://www.cms.gov/DemoProjectsEvalRpts/downloads/MID_FAQs.pdf

1) What degree of flexibility will conveners have with regard to the processes employed to deliver the DSS via the demonstration?

Conveners need to provide the DSS via either a POO or POS approach, but can, for example accommodate practices that may need to submit information via paper or by telephone. In terms of convenue submission of data to CMS, the conveners will need to submit data electronically via a secure transfer protocol established by CMS in the format laid out in the data specifications that appear on the web on a quarterly basis.

2) Given the complexity and requisite resources this initiative presents, will applicants be able to apply as co-conveners?

One legal entity will be asked to sign the terms and agreements – essentially, a contract with CMS. However, a proposal may come from entities working together for purposes of the demonstration project.

3) Will each convenue be permitted to use multiple technology platforms, or will each be required to use just one?

Each convenue will use one DSS, however, the DSS can employ multiple ways for a user to access the technology. In other words, a DSS could be embedded in an EHR or be access via a web based portal, however it would be the same DSS algorithm / logic that underlies the assessment of the appropriateness of the imaging order. It would be difficult for the evaluators to measure the use of a DSS if multiple DSS with differing underlying logic are used by one convenue.

4) Will conveners have the rights to publish the data generated by their physician panels?

No. Any use of data or information generated from the demonstration project will require CMS approval prior to publication.

5) How is a group practice defined?

For purposes of the demonstration, a group practice is defined as all providers using a Tax Identification Number (TIN), including all geographic locations should a group practice bill Medicare under one TIN; or all TINS should a group practice bill Medicare using multiple TINS.

6) The demonstration period will run for 2 years. When is the start date?

The law mandates a demonstration period of 2 years, which only applies to the pre-intervention period (the first 6 months) followed by the intervention (18 months), and an

evaluation period of 1 year after the conclusion of the demonstration. Start-up, implementation, and participant education will take place prior to the start of the 2-year demonstration period. We will be able to set key delivery dates once the conveners are selected.

7) Does the demonstration include inpatient, outpatient and emergency room imaging services?

The demonstration includes only advanced diagnostic imaging services (specifically, the 11 modalities identified) provided to Medicare fee-for-service beneficiaries paid under Part B. Inpatient (Part A) and emergency department imaging services are excluded. Services provided by an outpatient clinic (Part B) are included in the demonstration.

8) CMS does not expect applicants to actually develop a DSS unless/until selected by CMS for participation in the demonstration.

Applicants do need to describe in their proposal how the demonstration design addresses:

- convener responsibilities,
- physician practice responsibilities,
- DSS design features, functionality, and data flow to/from physician practices, and to/from CMS and its contractor;
- Project monitoring and evaluation requirements.

The proposal should identify and describe the DSS and its design features, functionality, technical specifications, system requirements, physician practice outreach and education. Specifically:

- How will the DSS meet the POS and POO definitions
- Describe how the DSS interface will provide transparency on the source of the medical specialty society guidelines included in this demonstration;
- Describe how the convener will address diagnoses not included in the medical specialty society guidelines included in this demonstration (e.g., other diagnoses related to the procedure, potential coding errors) and describe how the convener will address advanced diagnostic imaging services not included in the demonstration;
- Describe how the DSS will be integrated into the physician practice workflow;
- Describe how the DSS and physician practices will capture test results in the DSS. If applicable, describe the relationship between participating ordering physician(s) and rendering physician(s);
- Describe how the DSS captures the physician's attestation that the data to determine appropriateness and recommendations were reviewed by the physician and confirmed with the beneficiary;

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9) Can the DSS application utilize clinical literature and sources that go beyond the guidelines defined by CMS?

No. The law requires that the appropriateness criteria used in the demonstration be based on those developed or endorsed by medical specialty societies. For purposes of this demonstration, the “appropriateness criteria” referenced in the statute will be published medical specialty society guidelines relevant to the 11 procedures studied in the demonstration that are developed or endorsed by relevant medical specialty societies, and these guidelines will not differ across conveners.

Database structure and/or the clinical interface may not be altered during the course of the 2-year demonstration period. CMS will require conveners selected to participate in the demonstration to run test cases through their decision support system prior to collecting physician practice data to validate that the decision support system is in agreement with the specified guidelines. The results of the test cases will permit CMS to assess whether conveners’ implementation of medical specialty society guidelines is yielding sufficiently consistent appropriateness assessments or if system modification prior to implementation is required.

In addition, the demonstration relies on a pre/post research design which will allow CMS to measure the impact of using a DSS on the appropriateness of advanced imaging orders 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 and would be inordinately costly to perform through a retrospective review of medical records. The evaluation team will compare utilization during the baseline period with utilization during the same period of the previous year.

10) What is the maximum possible incentive payment for physicians?

The maximum possible incentive payment is approximately \$40,000 per practice over the course of the 2-year demonstration period and conditional on the historic ordering volume of the 11 procedures included in the demonstration.

The physician incentive payment will be based on a tiered system that accounts for the anticipated volume of reporting by each practice. Using claims data prior to demonstration initiation, CMS will classify physician practices into one of the five tiers based on historical (annual) ordering volume for the targeted advanced diagnostic imaging services under the demonstration. Incentive payments will be provided by the convener to each practice reaching the completeness of reporting (COR) minimum threshold as a fixed demonstration participation fee. The table (Exhibit 2) presents practice ordering volume tiers and estimated incentive payments for participating practices. The maximum annual payment per practice is \$20,000. Ultimately, the annual payment tiers for practices will be adjusted based on the actual historical ordering volumes, and the number and distribution of the physician practices selected to participate in the demonstration.

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11) Is there a penalty for not meeting the reporting requirements?

Payments are contingent on the physician practices and the conveners satisfying completeness of reporting (COR) requirements. For both physician practices and conveners, the COR threshold for year 1 of the demonstration is 80% of all targeted advanced imaging orders having been entered into the decision support system, and the COR threshold for year 2 of the demonstration is 90%.

12) For physician practice descriptions, what information goes on the worksheet? For the actual proposal, should we also describe in detail or can we put a reference to the worksheet?

A description of the physician practices should be part of the proposal, in addition to a more detailed identification of the practices using the worksheets.

Page 5 -- CMS is particularly interested in proposals from conveners that involve a diverse mix of physician practice sizes (e.g., small practices), medical specialties (e.g., primary care and cardiology), geographic location, demographic characteristics, and practice types. CMS will consider the characteristics of the physician practices and the ability of the convener to perform the functions identified in this solicitation when selecting demonstration areas. Preference will be given to applicant conveners who include primary care physicians and cardiologists who serve geographic areas with a range of population densities, demographic characteristics, and academic and private settings. Physician practices apply through a convener and the convener's application must include the criteria and rationale for recruiting physician practices and obtaining their buy-in for the use of the DSS.

Page 14 -- Description of the Physician Practices recruited for participation in the MID: Applicants must describe the proposed physician practices recruited for participation in the MID, including but not limited to the following: • Identify the name of the practice, all practice TINs, the number of practice physicians, and the physician medical specialties. Please identify recruited physician practices and their letters of intent (an optional Excel worksheet is provided) • Provide an estimate of the number of Medicare FFS beneficiaries served by the practice; • Provide an estimate of the number of advanced diagnostic imaging services performed for Medicare FFS beneficiaries by the practice; • Specify any ownership of and type of advanced diagnostic imaging equipment; • Specify practice's use of electronic health records; • Specify practice's experience with the DSS for ordering of advanced imaging procedures; • Identify any physician practice recruited that is participating in any other CMS demonstration. (NOTE: CMS will determine if overlap of demonstration projects or concurrent participation in more than one demonstration project will affect the evaluation of the demonstration(s)); and • Describe the criteria by which physician practices are recruited.

13) What are the preferred characteristics or qualifications of the MID project manager / liaison to CMS, if any? For example, would you prefer this person be a physician, and IT professional, executive from within the convener organization, or a business manager?

In evaluating each proposal, CMS will be looking at how the applicant proposes to meet all the convener responsibilities outlined in the solicitation (starting on page 4). Therefore, the proposed personnel qualifications should reflect the roles and tasks associated with the proposal.

14) Is there more information on what items should be considered in the budget in addition to the small section in the Solicitation for Proposals document?

At a minimum, applicants should include the following:

- A proposed convener budget for implementing a 2-year demonstration, including performing all convener functions outlined in this solicitation and providing DSS to physician practices; and
- A description of any non-monetary incentives that may be made available to physician practices under the demonstration.

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For example, conveners will be responsible for recruiting physician practices, deploying a DSS that incorporates medical specialty society guidelines for the selected procedures, ensuring the DSS remains current with those guidelines, collecting and transmitting data, and distributing payments to practices for reporting data. CMS is particularly interested in proposals from conveners that involve a diverse mix of physician practice sizes and types, medical specialties, and geographic areas.

CMS will consider the characteristics of the physician practices and the ability of the convener to perform the functions identified in the solicitation when selecting demonstration areas. Convener applications will be reviewed and rated by a panel established by CMS, based on the evaluation criteria provided in the solicitation. Based on the panel's recommendation, the CMS Administrator will select the applicants to be offered participation in the demonstration. Selected conveners will be required to agree to the terms and conditions of participation prior to implementation of the demonstration.

15) Is every convener expected to provide geographic and practice diversity or will CMS expect to achieve diversity through approval of multiple conveners?

Conveners will be selected based on meeting the requirements outlined in the solicitation, including organizational structure, operational feasibility, soundness of demonstration design, and representativeness of the physician practices panel including a mix of urban, rural and suburban areas. Preference will be given to applicant conveners who include primary care physicians and cardiologists who serve geographic areas with a range of population densities, demographic characteristics and academic and private settings. Selection of conveners will depend to a smaller extent on the mix of practices among all conveners.

16) Does the \$10 million includes the incentive payments for the ordering physicians or is there additional money for incentives?

The \$10 million includes the incentive payments to physicians and conveners. Congress provided \$10 million for carrying out the demonstration project including costs associated with administering the demonstration, incentive payments, and evaluating the demonstration project.

17) Will CMS accept conveners that include multiple organizations?

One legal entity will be asked to sign the terms and agreement – essentially, a cooperative agreement with CMS. However, a proposal may come from entities working together for purposes of the demonstration project.

18) For point of order systems, will all physicians have to use DSS for all of the 11 exams or can a subset be selected as long as the minimum volumes are achieved? If physicians can report a subset of the 11 examinations, do conveners have to recruit physicians so that all 11 exams will be reported or can they focus on a subset of the 11?

Participants must use a demonstration decision support system as described in the solicitation for the targeted advanced diagnostic imaging services ordered by the physician practice for Medicare fee-for-service beneficiaries. All physicians in a participating practice must use a decision support system (and the convener must submit) for all orders for the 11 targeted procedures.

While the demonstration will focus on the 11 selected procedures, to avoid confusion, physician practices should be instructed to enter all advanced imaging tests for Medicare beneficiaries into the decision support system. The DSS must be designed to distinguish between the 11 procedures targeted by the demonstration, and other procedures; the DSS should not be designed to provide information for only a subset of the 11 demonstration procedures.

Ultimately, CMS will need specific numbers of each of the advanced diagnostic imaging services included in the demonstration to calculate statistically valid results. At this point, it is impossible for us to predict whether or not a proposal that focuses on only a subset of the 11 services would be competitive when reviewed against other proposals.

19) Is the money used to provide DSS software and training to participants part of the budget and not considered an incentive?

Funding for DSS software and training to participants should be included in the convener's proposed budget. CMS will determine the amount paid to conveners meeting the COR performance standard based on the budget proposed by the convener and accepted by CMS.

20) Are the guidelines listed on the CMS website for the imaging demonstration the latest guidelines?

The list of guidelines posted on the MID website are the guidelines that were current as of May 2010. We are aware that recently there have been some updates to guidelines. We wanted to provide potential applicants with some general guidance about the guidelines that would be used for the demonstration, but recognizing that between the time of the announcement of the demonstration and the actual selection of participants there could be changes. Also as indicated in the solicitation, we understand that guidelines will continue to change during the demonstration period. Once demonstration convener participants are selected, we expect to work with the selected conveners and the medical specialty societies to identify the most recent guidelines that should be used at the start of the demonstration.

In their proposal, applicants will need to describe the approach they will use to update their DSS as guidelines change during the course of the demonstration, but are not expected to make changes to their DSS for purposes of applying for the demonstration. However, DSS changes to accommodate the technical requirements of the demonstration will be required by applicants chosen to participate in the demonstration.

21) The codes for SPECT MPI appear to be older codes can you provide the applicable updated codes?

The codes for SPECT MPI changed in 2010. Codes 78464 and 78465 are being replaced by 78451 and 78452.

22) How will the financial incentive system work?

CMS will pay participating practices based on historic ordering volume. Historical volume calculations will be based on Medicare claims data and apply only to those 11 procedures included in the demonstration, ordered for Medicare fee-for-service patients. Participating physician practices will be classified into volume tiers based on the prior year's ordering history volume of the 11 procedures, and paid fixed annual payments based on the tier to which they are assigned. The payment will be paid semi-annually, and will be subject to the practice submitting complete and accurate data. CMS will determine the payment amount to the practices. Therefore, there is no incentive for increasing or decreasing the number of advanced diagnostic images ordered during the demonstration.

Under the demonstration, CMS is paying for data. Payment to physician practices is contingent on a completeness of reporting (COR) threshold. At minimum, a practice must have used the decision support system for at least 80% of eligible orders in year 1 of the demonstration, and at least 90% of eligible orders in year 2 of the demonstration. The incentive payments for physicians are independent of Medicare reimbursement, and the estimated payment amounts described in the solicitation are comparable with what the actual incentive payment will be.

Convener payments will be contingent on meeting quality and COR requirements. COR for each convener is calculated using the aggregate of all eligible orders across all physician practices and determining the proportion of which were entered into the decision support system. The convener COR threshold for year 1 of the demonstration is 80% of all targeted advanced imaging

orders having been entered into the decision support system, and the COR threshold for year 2 of the demonstration is 90%. Convening entities will submit proposed bids for their payment amount as part of the demonstration application process. Payments to conveners will follow a similar schedule as those to physician practices (i.e., semi-annually).

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23) What documents/forms exactly need to be in our application?

There is a link titled “Demonstration Application” provided on the project webpage. This zipped file contains 1) Form 10069; 2) clarification for completing Form 10069; and 3) a “MID Application Checklist.”

The checklist specifies all the components necessary to complete the application:

- ✓ Form 10069
- ✓ MID Convener Summary Worksheet (request from MID@lewin.com)
- ✓ MID Practice Workbook (request from MID@lewin.com)
- ✓ Proposal (applicant’s response to Solicitation)