Medicare Imaging Demonstration Frequently Asked Questions

Table of Contents

I.	Medicare Waiver Demonstration Application Form (CMS Standard Form 10069) and Medicare Imaging Demonstration Solicitation	
	Questions 1-13	2
II.	Medicare Imaging Demonstration	
	Background Information	
	Questions A.1-A.10 Decision Support Systems	5
	Questions B.1-B.7 Targeted Procedures	9
	Questions C.1-C.5	12
	Questions D.1-D.3 Incentive Payments	14
	Questions E.1-E.6 Demonstration Participation and Protocol	16
	Questions F.1-F.14	19
	Questions G.1-G.3 Feedback Reports	23
	Question H.1	24

I. Medicare Waiver Demonstration Application Form (CMS Standard Form 10069) and Medicare Imaging Demonstration Solicitation

Questions & Answers

Ouestions 1-13

Question #1:

How do I complete the box for Applicant's Medicare Provider Number(s) on the first page of the form (Medicare Waiver Demonstration Applicant Work Sheet)?

Answer #1:

If the organization applying to become a convener is not a Medicare provider, please enter "Not Applicable".

Question #2:

How do I respond to the question about whether the Applicant is a Medicare Provider/Organization in Good Standing on the first page of the form (Medicare Waiver Demonstration Applicant Work Sheet)?

Answer #2:

If the organization applying to become a convener is a provider, indicate on the form whether the convener is a provider in good standing. However, if the convener is not a provider, indicate that on the form. Regardless of whether the convener is a provider, all applicants must indicate whether the physicians on their panels are providers in good standing with Medicare.

Question #3:

How do I respond to the discussion of Medicare-waiver-only demonstrations on the second page of the form?

Answer #3:

Not Applicable.

Question #4:

On the second page of the form, there is a section on budget neutrality. Does this apply to my application?

Answer #4:

Not Applicable.

Question #5:

On the third page of the form under the Application Requirements section, it states that in the cover letter, we should identify our proposed target population. Does this apply?

Answer #5:

The Medicare Imaging Demonstration will only involve Medicare fee-for-service beneficiaries.

Question #6:

On the third page of the form under the Application Requirements section, it states that in the cover letter, we should list the CMS provider numbers assigned to the applicant. Does this apply?

Answer #6:

If the convener is a provider, please list the CMS provider number. If the convener is not a provider, it is not necessary to list a provider number, and just indicate that the convener is not a provider.

Question #7:

On the third page of the form under the Application Requirements section, it states that in the problem statement, we should describe how changes to current Medicare coverage and payment policy would lead to reductions in Medicare expenditures or improvements in Medicare beneficiaries' access to and/or quality of care. Does this apply?

Answer #7:

Because the Medicare Imaging Demonstration does not involve changes in Medicare coverage or payment policy, this information does not need to be included in the problem statement. See the solicitation for specific instructions on the proposal requirements.

Question #8:

On the third page of the form under the Application Requirements section, it states that in the demonstration design section, we should describe the intervention including the scope of services covered and/or benefit design, and payment methodology including financial incentives and/or risk sharing arrangements. Does this apply?

Answer #8:

The Medicare Imaging Demonstration does not involve an intervention that changes Medicare coverage, benefit design, or payment methods. See the solicitation for specific instructions regarding what applicants need to describe in terms of the demonstration design section of their proposal.

Question #9:

On the third page of the form under the Application Requirements section, it states that in the demonstration design section, we should indicate how eligible beneficiaries will be identified, targeted, and enrolled in the demonstration. Does this apply?

Answer #9:

No. The Medicare Imaging Demonstration does not involve the enrollment of beneficiaries in this demonstration; consequently applicants do not need to address this in their submissions.

Question #10:

On the fourth page of the form under the Application Requirements section, does the Payment Methodology & Budget Neutrality section apply to this demonstration?

Answer #10:

No. Because the Medicare Imaging Demonstration does not involve setting payment rates or risk sharing and has a budget established by statute, this section does not need to be addressed. Applicants, however, should see the solicitation for specific instructions regarding proposed budget and incentive payments.

Question #11:

On the fourth page of the form under the Application Requirements section, it states that in the Demonstration Implementation Plan that we need to describe our recruitment strategy and contingency plans for achieving beneficiary participation thresholds. Does this requirement apply to this demonstration?

Answer #11:

The Medicare Imaging Demonstration does not involve the enrollment of beneficiaries; therefore you do not need to address a beneficiary recruitment strategy in your applications. However, you should address your strategy for recruiting physician practices in this section. See the solicitation instructions regarding description of physician recruitment.

Question #12:

The solicitation requests that applicants in describing physician practices recruited for participation in the Medicare Imaging Demonstration provide an estimate of the number of advanced imaging services performed for Medicare fee-for-service beneficiaries by the practice. Does this request apply to practices that only order advanced imaging services but do not actually perform the imaging study?

Answer #12:

The request applies to both practices that perform studies and practices that only order studies. Please provide an estimate of the number of advanced imaging services that were provided to Medicare fee-for-service beneficiaries seen by the practice.

Ouestion #13:

Where can I send questions about the solicitation?

Answer #13:

If you have questions about the solicitation, please send an email to <u>ImagingDemo135b@cms.hhs.gov</u>.

II. Medicare Imaging Demonstration

Background Information

Questions A.1-A.10

Question #A.1:

What is the purpose of the Medicare Imaging Demonstration (MID)?

Answer #A.1:

The 2-year demonstration will assess the impact that decision support systems (DSSs) used by physician practices have on the appropriateness and utilization of advanced medical imaging services ordered for the Medicare fee-for-service population.

Question #A.2:

What are conveners and who can serve as conveners in the demonstration?

Answer #A.2:

CMS anticipates we will reach the physicians interested in participating and the number of physicians needed to participate in the demonstration more efficiently and more effectively through a "convener." Conveners will be responsible for recruiting physician practices, bringing a decision support system (DSS) that is specific to the selected procedures and guidelines, ensuring the DSS remains current with those guidelines, collecting and transmitting data, and distributing payments to practices who are reporting data.

A convener can be an entity (e.g., medical specialty organization, large group multispecialty practice, decision support system vendor, radiology benefit manager) which meets the defined criteria and performs the functions described in the solicitation.

Question #A.3:

How can a physician practice apply to participate?

Answer #A.3:

The convener's proposal must include a completed list of physician practices applying to participate in the demonstration including information about the physician practice such as ownership of equipment for advanced imaging services, Tax Identification Number, and other practice characteristics.

Convening entities will recruit physician practices, ensure a DSS specific to the selected procedures and guidelines is used by participating practices, ensure the DSS remains current with guidelines, collect data from physician practices and transmit it to CMS, and distribute payment to practices for reporting data. CMS will determine the payment amount to the practices.

Although the MID is exempt from the Paperwork Reduction Act, we are using the existing demonstration application form (CMS-10069 (08/06); OMB No. 0938-0880) as a template to capture the information needed to evaluate the proposals. We have modified the directions where necessary to reflect the requirements of this demonstration. For example, we request information regarding how the project budget would be spent, however a discussion of involving budget neutrality is not applicable under this demonstration and therefore not required.

Ouestion #A.4:

How wide a geographic area must a convener bring?

Answer #A.4:

CMS is particularly interested in proposals from conveners that involve a diverse mix of physician practice sizes, medical specialties, 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 the 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.

Question #A.5:

Why would a physician practice want to participate in this demonstration?

Answer #A.5:

This is an opportunity for physician practices to test whether the use of a DSS can improve 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. CMS will pay physician practices for data, and physician practices will be provided with feedback reports so that they know how they are performing relative to the appropriateness criteria, and to their peers under the demonstration.

Question #A.6:

Why would a beneficiary want his or her physician to participate in the demonstration?

Answer #A.6:

Imaging technology has dramatically advanced the power of medical diagnostics, providing critical tools for physicians to diagnose disease through noninvasive approaches. The use of advanced imaging techniques has the potential to improve patient care through earlier detection that may reduce downstream morbidity and mortality, however overuse and/or misuse may cause more harm than good.

Question #A.7:

How did CMS calculate the proposed recruitment size (200-1000 physicians per convener) and does it incorporate various geographies and practice type and size that might otherwise be included in the demonstration?

Answer #A.7:

Our design and implementation contractor looked at the number of advanced diagnostic images needed to yield a large enough sample size to generate statistically significant results. To achieve adequate sample sizes of imaging services based on a total number of practices for each convener, we assumed approximately 200-1,000 physicians. The physicians should come from practices that vary in size, specialty mix, type, and geographic location.

Question #A.8:

How will CMS obtain a broad representative cross-section population of practicing physicians for the demonstration? Sampling a volunteer population of physicians could have inherent selection biases and therefore potentially represent a skewed population of physicians being sampled.

Answer #A.8:

Participation in this demonstration is voluntary and self selection biases may occur. In reviewing the applications for participation in the demonstration, CMS will consider the physician practices across practice size, type, and physician specialty recruited by the conveners. The pre-post demonstration design will provide a baseline from which to measure current compliance with appropriateness criteria as well as changes during the demonstration. Using claims data, we will also compare utilization during the demonstration and baseline periods with utilization during the same period of the previous year to determine changes in ordering practices and utilization.

Question #A.9:

There may be an artificially lowered baseline level of appropriateness rates because of the potential "sentinel" effect that may occur during the baseline collection of data, as physicians are aware they are participating in the demonstration. How is this being addressed?

Answer #A.9:

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.

Question #A.10:

How will CMS address the impact of changes in payment authorized by the recent law (the Affordable Care Act) that may occur during the demonstration?

Answer #A.10:

The design of the evaluation should permit analyses to control for effects of payment changes. Under the pre/post design, changes in use of imaging services may reflect the total of demonstration and other payment change effects. However, we will be supplementing analysis with changes in use of imaging prescribed by a separate comparison group of providers ordering imaging services. Analysis of changes in prescribing behavior by this latter group over the time period covered by the demonstration will help us identify effects due solely to (non-demonstration) payment changes. These latter effects will then be used in conjunction with pre/post effects to estimate effects of the demonstration proper.

Decision Support Systems

Ouestions B.1-B.7

Question #B.1:

What data and communication capabilities are required of a physician practice for participation in the demonstration?

Answer #B.1:

Physician practices must have the appropriate internet access, or other data and communication capabilities, in order to:

- 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, and support electronic and secure data transmission to/from CMS through the convener. Physician practices may or may not directly enter data via a Web portal or a decision support system integrated into the provider's electronic health record system. However, all physicians in a participating practice must use a decision support system and the convener must submit all orders for the 11 targeted procedures electronically to CMS.
- Receive feedback from a decision support system on appropriateness of order (except during the baseline data collection period).
- Participate in the demonstration evaluation by providing and updating as needed, information on practice characteristics as specified in the solicitation.
- Participate in a physician practice satisfaction survey during the intervention period if requested by CMS.

Question #B.2:

How are decision support systems, including point of order (POO) and point of service (POS), defined for this demonstration?

Answer #B.2:

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 statute describes two types of decision support models to be included in the demonstration: POO and POS. The statute describes POO models as computerized order-entry systems that require input of relevant supporting information at time of referral for advanced imaging services, and provides automated decision support

feedback to referring physicians regarding appropriateness of the order. The statute describes POS as using either an electronic or paper intake form that the physician practice furnishing the imaging services uses to confirm information with the beneficiary, and contains certain data elements (e.g., diagnosis, service ordered, service furnished). The POS model also provides feedback regarding the appropriateness of the order. The POS model must allow for electronic submission of the information.

Question #B.3:

Will CMS be selecting or evaluating the performance of different decision support systems in their impact on physician ordering behavior?

Answer #B.3:

No. The goal of demonstration is not to compare DSSs. The demonstration will examine the impact of using a DSS on the rate of ordering and on the appropriateness of ordered advanced imaging services. The demonstration will include ordering related to three advanced imaging modalities: MRI, CT, and nuclear medicine. Within those modalities, the demonstration will target appropriateness of ordering for 11 targeted advanced imaging procedures that are among the most commonly used advanced diagnostic imaging services in the Medicare FFS population. The demonstration relies on specified medical specialty society guidelines for these 11 procedures that must be transparent in the DSS used under the demonstration.

Question #B.4:

Does a convener have to provide both point of order (POO) and point of service systems (POS)?

Answer #B.4:

The MIPPA states that both POO and POS models must be included in the demonstration. In order to satisfy this requirement, conveners need to describe their decision support systems as they relate to the POO and POS models.

Conveners will be selected based the merit or quality of the proposals submitted. CMS will select up to six conveners depending on sample size and budget limitations.

Question #B.5:

What data and communication capabilities are required of a convener for participation in the demonstration?

Answer #B.5:

Conveners must arrange for the availability of POO and POS systems for physician practices participating in the demonstration, including decision support for ordering of the 11 targeted procedures in the demonstration and described in the solicitation.

Conveners must also be able to submit quarterly data via a secure FTP site in a format to be specified by CMS' demonstration design and implementation contractor.

Question #B.6:

How and to whom do conveners or physicians submit data?

Answer #B.6:

The ordering of advanced imaging services for Medicare fee-for-service beneficiaries by physician practices will be captured by the decision support systems. Conveners will be required to submit this data to the CMS demonstration design and implementation contractor quarterly, via a secure FTP site. All data collection and submission must comply with privacy and security requirements.

Question #B.7:

Since each decision support system is different, how will CMS deal with variations in how decision support systems assess appropriateness of services?

Answer #B.7:

There are 11 targeted advanced diagnostic imaging procedures within the 3 designated modalities (MRI, CT, and SPECT-MPI) that have been selected for inclusion in the demonstration. 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.

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.

Targeted Procedures

Ouestions C.1-C.5

Question #C.1:

How were the 11 procedures targeted for inclusion in the demonstration chosen?

Answer #C.1:

MIPPA statute specifically requires the inclusion of MRI, CT and nuclear medicine in the demonstration. The 11 procedures selected for inclusion in this demonstration were based on the following criteria:

- Represent a large share of expenditures under the Medicare program or experienced a high rate of growth;
- Are covered by appropriateness criteria developed or endorsed by a medical specialty society; and,
- Evidence of variation in utilization rates or appropriate use Stakeholders, including medical societies, health plans, medical providers, radiology benefit managers, software developers of decision support systems, and others, provided feedback on which procedures best met the necessary criteria. The 11 procedures selected are among the most common advanced imaging diagnostic services provided to Medicare beneficiaries, and for which there are medical specialty society appropriateness criteria.

Question #C.2:

Are conveners responsible for providing decision support for procedures not included in this demonstration?

Answer #C.2:

Conveners are responsible for providing decision support for the 11 procedures included in this demonstration and, in their proposals conveners are expected to address how they will treat advanced imaging services not included in this demonstration. Decision support systems must be transparent in regard to the appropriateness criteria used and about the inclusion/exclusion of procedures in the demonstration.

Question #C.3:

Will Medicare pay providers for advanced imaging services scored as "inappropriate?"

Answer #C.3:

This demonstration does not change any Medicare coverage or payment policy; nor does it allow prior authorization.

Question #C.4:

Since CMS is targeting only certain procedures, won't this be confusing to physician offices about when they need to use decision support systems?

Answer #C.4:

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 decision support system will make the distinction between procedures included and not included in the demonstration. In their proposals, conveners are expected to address how they will treat advanced imaging services not included in the demonstration.

Question #C.5:

Can a convener choose to only deal with a subset of the 11 selected procedures?

Answer #C.5:

Ultimately, CMS must meet the requirements of the law by assessing the impact of using a DSS (POO and POS models) by physician practices have on the appropriateness and utilization of CT, MRI and nuclear imaging services ordered for the Medicare fee-for-service population.

Conveners will be selected based the merit or quality of the proposals submitted. CMS will select up to six conveners depending on sample size requirements and budget limitations.

Medical Specialty Society Guidelines

Questions D.1-D.3

Question #D.1:

How were the appropriateness criteria guidelines selected for inclusion in the demonstration chosen?

Answer #D.1:

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 guidelines identified for inclusion in the demonstration were developed or endorsed by thirteen separate medical specialty societies, with the following seven societies serving as the primary sponsoring entity: American College of Radiology; American Academy of Neurology; American College of Cardiology; American Academy of Otolaryngology; American College of Physicians; American Pain Society; and, North American Spine Society. These societies often work in collaboration in the creation of appropriateness criteria and guidelines.

The medical specialty society guidelines generally applied common development processes and are consistent with appropriateness criteria principles described by the AQA Alliance (in October 2007 and revised in June 2009), including with the following:

- Blend of evidence-based literature and expert opinion;
- Use of expert panels consisting of multidisciplinary clinicians;
- Employ a modified Delphi technique or similar process;
- Inclusion of multiple clinical scenarios and consideration of benefits and risks;
 and
- Periodic scheduled review processes to update criteria and guidelines to reflect new evidence.

In addition, we vetted the demonstration design with the public and asked for comment on the modalities and guidelines chosen for use in the demonstration. We incorporated feedback from two Open Door Forums into the design.

Question #D.2:

How are diagnoses without consensus guidelines dealt with?

Answer #D.2:

CMS has identified the medical specialty society guidelines that are relevant to the 11 imaging procedures in the demonstration. However, some diagnoses may not be included in the selected guidelines and conveners will be required to address how they will deal with this in their proposals (e.g., other diagnoses related to the procedure, potential

coding errors). Under the demonstration, decision support must be transparent as to the source of medical specialty society guidelines used to provide decision support to physicians. CMS will work with the conveners around appropriate messaging for clinical scenarios not addressed by the identified guidelines.

Question #D.3:

How does CMS intend to deal with differences among medical specialty society guidelines?

Answer #D.3:

In general, we find that where multiple medical societies have promulgated appropriateness guidelines that are relevant to the procedures we are targeting, the societies have issued guidelines collaboratively, or there is concordance across guidelines. We are aware of a limited set of areas where there may be some differences. Under the demonstration medical specialty society guidelines must be transparent to the physician. The appropriateness assessments would need to accommodate a determination that a procedure is appropriate, if such a determination is consistent with any of the applicable medical specialty society guidelines.

Incentive Payments

Questions E.1-E.6

Question #E.1:

How will the financial incentive system work?

Answer #E.1:

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).

Ouestion #E.2:

Are conveners allowed to offer additional incentives to physician practices for participation in the demonstration?

Answer #E.2:

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.

Question #E.3:

How will payment be made?

Answer #E.3:

CMS will provide payment to each convener. CMS will determine the amount paid to each participating physician practice meeting the COR performance standard based on the practice's historic annual ordering volume. 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.

Payments to conveners and participating physician practices will occur four times throughout the demonstration, at approximately six month increments. The conveners are expected to distribute payments (as determined by CMS) to the participating physician practices.

Payments are contingent on both 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%.

Question #E.4:

How is completeness of reporting (COR) determined?

Answer #E.4:

COR will be measured by matching the number of decision support system records captured to the number of advanced imaging service claims for the 11 target procedures found in the Medicare fee-for-service claims data. COR will be measured at both the practice level and at the convener level. The COR threshold for year 1 of the demonstration is 80 percent (i.e., no less than 80 percent of the tests ordered must have a decision support system record) and the COR threshold for year 2 is 90 percent. The goal is to encourage conveners to collect complete data from the practices for the targeted 11 advanced imaging procedures.

Question #E.5:

If conveners cannot guarantee practices a certain payment amount, won't this be a problem in trying to recruit practices to participate as part of the application process?

Answer #E.5:

CMS is paying for data collected during this demonstration. Payments to physician practices are contingent on a completeness of reporting (COR) threshold. 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. Physician practices will be classified into volume tiers based on their prior year's ordering history volume of the 11 procedures, and participating practices will be paid fixed annual payments based on the tier to which they are assigned.

Question #E.6:

Who determines the historic ordering volume of a practice – the practice, the convener, or CMS?

Answer #E.6

As part of the proposals, conveners will submit the Practice Work Sheets that provide CMS with the necessary information needed for the research contractor to analyze the historic Medicare claims data. Claims data for advanced diagnostic imaging services include the NPI for both the ordering and rendering physicians. The information from the Practice Work Sheet will allow us to calculate the historical ordering volume of each physician practice and estimate annual payments under the demonstration based on the tier to which they are assigned.

Demonstration Participation and Protocol

Questions F.1-F.14

Question #F.1:

How much will conveners be paid?

Answer #F.1:

Conveners must submit a proposed budget as part of their application to participate. 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.

Question #F.2:

Can a hospital participate in the demonstration?

Answer #F.2:

A physician practice affiliated with an outpatient ambulatory care hospital is eligible for participation in the demonstration. However, all physicians in the practice ordering advanced imaging services for Medicare fee-for-service beneficiaries must participate in the demonstration and use the decision support system to order the demonstration's 11 targeted advanced imaging services for Medicare beneficiaries.

Question #F.3:

Are any provider specialties excluded from participation in this demonstration?

Answer #F.3:

No practices or specialties meeting demonstration requirements are excluded from participation.

Question #F.4:

Is it required that all of the physicians within a participating practice participate in the demonstration?

Answer #F.4:

If a practice is chosen for participation in this demonstration, all physicians in that practice are required to participate in the demonstration and must agree to cooperate with the evaluation (including reporting of data and responding to intake and evaluation surveys).

Question #F.5

Can nurse practitioners and physician assistants participate in this demonstration?

Answer #F.5:

For physician practices located in States that permit non-physician practitioners to order imaging services, and if the practices employ non-physician practitioners, then orders by these non-physician practitioners need to be included. In addition, non-physician practitioners need to be identified in the Practice Work Sheet submitted as part of the convener's proposal.

Ouestion #F.6:

Are physicians who actively practice in more than one practice eligible for participation in the demonstration? Can a physician or physician practice participate in more than one convener's panel?

Answer #F.6:

Yes, however, physicians and physician practices may only participate with a single convener. The convener's proposal must include a completed list of participating physician practices (e.g., practice Tax Identification Number (TIN)). All physicians in a given practice must agree to participate in the demonstration and must agree to cooperate with the evaluation (including reporting of data and responding to intake and evaluation surveys).

Ouestion #F.7:

Are Federally Qualified Health Centers excluded from participation?

Answer #F.7:

Any practice meeting the requirements of the demonstration are eligible for participation. If a practice is chosen for participation in this demonstration, all actively practicing physicians within that practice are required to participate and to cooperate with the evaluation of the demonstration, including entering and reporting of data and responding to the evaluation surveys.

Question #F.8:

Will participation in this demonstration affect current practice methods of submitting claims or billing Medicare?

Answer #F.8:

No. Current practice methods of submitting claims or billing to Medicare will not be affected by participation in this demonstration. The demonstration does not change Medicare coverage or payment policies.

Question #F.9:

Do physicians need informed consent from all of their Medicare patients in order to participate in this demonstration?

Answer #F.9:

This demonstration does not affect Medicare benefits or payments. Conveners and physician practices are encouraged to inform beneficiaries of their participation, but the demonstration does not require patient consent.

Question #F.10:

What is the impact on a convener if one of its physician practices drops out?

Answer #F.10:

Physician practice participation throughout the demonstration period is essential, and practices will receive incentives for such participation. CMS expects that practices volunteering for participation in this demonstration will remain as participants for the entire demonstration period. Nevertheless, in developing the application for this demonstration, a convener must include a plan for how they anticipate handling physician practice attrition and turnover of physicians within practices, so that an adequate sample of physicians is maintained.

Question #F.11:

How much time will conveners have to adapt or build and test decision support systems?

Answer #F.11:

In the solicitation, conveners are asked to estimate the time needed to prepare decision support systems for demonstration implementation. As a part of the competitive process for conveners, CMS will take into consideration the time needed by a convener to adapt their decision support system.

Question #F.12:

Is the implementation date of the demonstration a specific date, or will a "rolling" start be allowed?

Answer #F.12:

CMS believes it is important to have all demonstration conveners implement their decision support systems on the same time schedule. Conveners will also be expected to implement systems across all participating practices on the same schedule.

Question #F.13:

What role will rendering physicians/radiologists play in the demonstration?

Answer #F.13:

The focus of this demonstration is on the appropriateness of ordering of advanced diagnostic imaging services. Both ordering and rendering physicians can play a role in assuring the appropriateness of use of advanced diagnostic imaging services. The composition of the physician practice panels will be based on convener recruitment and CMS is not specifying a specific role for ordering versus rendering physicians under the demonstration. Conveners will need to assure that only a single record for a specific order for a patient is created in the decision support system.

Question #F.14:

The solicitation mentions that there is a five-claim minimum ordering volume for participants. Does this mean there is a five-claim minimum for each individual physician or for each participating practice? Also, does this minimum mean that participating physicians need to have ordered tests in at least five of the 11 categories?

Answer #F.14:

Our goal is to include both high-volume and low-volume ordering physicians and to encourage participation of low-ordering practices. We will be looking for claims for the 11 selected procedures ordered by a practice and for a minimum of 5 claims (per practice) during the prior year. It is not 5 of the 11 procedures, rather a minimum of 5 claims of any of those 11 procedures included in the demonstration for which there are claims during the prior year by the practice. For example, all 5 claims may be for the same procedures (e.g., CT Brain); this would qualify as the minimum ordering volume.

Work Flow

Questions G.1-G.3

Question #G.1:

Will there be instances where the physician's office is required to call the decision support system provider/convener for a consult regarding the order of an advanced imaging procedure for a patient?

Answer #G.1:

No. The Medicare Imaging Demonstration does not involve a prior authorization or notification process. It is focused on physician education/practice improvement through the use of decision support systems based on medical specialty society guidelines and the use of profile feedback reports. Conveners may offer to physician practices to collect data for entry into a decision support system via the telephone.

Question #G.2:

How does CMS envision the use of the decision support system being integrated into the physician office workflow?

Answer #G.2:

Conveners must arrange for the availability of POO and POS systems for their panel of physician practices participating in the demonstration. The authorizing physicians in the practice will determine the specific office workflow process for use of the decision support system.

In order to facilitate physician practices' office workflow processes and avoid potential confusion, CMS anticipates that conveners will have their participating physicians use the decision support system for all orders of MRI, CT, and nuclear medicine imaging procedures for Medicare fee-for-service beneficiaries. The decision support system will make the distinction between procedures included and not included in the demonstration. Conveners are expected to address in their proposals how they will deal with such procedures.

Question #G.3

During the demonstration, who will be providing technical assistance to physician practices if they have questions?

Answer #G.3:

The physician practices should contact conveners for any ongoing technical assistance or questions regarding the DSS and/or data problems. The conveners are responsible for having in place mechanisms to educate practices on the use of the DSS and demonstration requirements. The conveners are also responsible for monitoring participating practices' compliance with pay for reporting requirements and for handling the demonstration incentive payment to the practices.

Feedback Reports

Question H.1

Question #H.1:

What type of feedback will physician practices receive?

Answer #H.1:

In addition to receiving immediate feedback on appropriateness of a specific order at the time an order is entered into a decision support system, there will also be periodic, confidential feedback reports. These reports will provide physician practices with information on appropriateness of orders, rates of ordering, and test results. The reports will provide data on appropriateness and utilization of advanced diagnostic imaging services compared with aggregate data on other physician practices at the convener level and the demonstration level. We expect to work with conveners and the participating practices in designing feedback reports that will provide useful information to the practices.