Solicitation for Proposals for the Medicare Imaging Demonstration

I. Introduction

Section 135(b) of the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) instructs the Secretary to conduct a demonstration to collect data regarding the appropriateness of physician use of advanced diagnostic imaging services. The goal of the Medicare Imaging Demonstration (MID) is to collect data regarding physician compliance with appropriateness criteria selected by the Secretary under the terms of the statute in order to determine the appropriateness of advanced diagnostic imaging services furnished to Medicare beneficiaries. The authorizing legislation allows the Secretary to include in the demonstration advanced diagnostic imaging services such as those defined in section 1834(e)(1)(B) of the Social Security Act: diagnostic magnetic resonance imaging (MRI), computed tomography (CT), nuclear medicine (including positron emission tomography), and such other diagnostic imaging services, including services described in section 1848(b)(4)(B) (excluding X-ray, ultrasound, and fluoroscopy). The law prohibits the use of prior authorization in the demonstration.

The statute permits the Secretary to focus the demonstration on advanced diagnostic imaging services that: (1) account for a large share of expenditures; (2) have experienced a high rate of growth; or (3) are services for which clinical appropriateness criteria exist. There are 11 targeted advanced diagnostic imaging procedures within the 3 designated modalities (MRI, CT, and nuclear medicine) that have been selected for inclusion in the demonstration (see Section II.B.). 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, are consistent with the spirit of section 135(b)(2)(B)(ii)(II), and which have been selected by the Secretary under the terms of the statute. (We believe the appropriateness criteria are the product of consensus and meet the spirit of section 135(b)(2)(B)(ii)(II) of MIPPA. Accordingly, the Centers for Medicare & Medicaid Services (CMS) worked with medical specialty societies and other stakeholders, including the AQA Alliance, to obtain their input and information on available appropriateness criteria. Consequently, published medical specialty society guidelines relevant for the 11 procedures are included in the demonstration.

The demonstration will test whether the use of decision support systems (DSSs) can improve quality of care and reduce unnecessary radiation exposure and utilization by promoting appropriate ordering of advanced imaging services. Physician practices will receive feedback on the degree of appropriateness relative to the specified medical specialty society guidelines used under the demonstration provided at the time of order entry into the DSS. Participating physicians also will be provided with periodic feedback reports that compare their ordering patterns against those of their peers. The demonstration will assess the effect of feedback reports on physicians' ordering behavior.

The design of the demonstration will permit evaluation of the appropriateness of imaging services across a range of advanced diagnostic imaging studies, geographic areas, demographic characteristics, and practice settings (such as private and academic practices) in the Medicare fee-for-service (FFS) program. CMS is seeking participation by 2,500 to 3,500 physicians from 500 to 650 physician practices that vary in size, specialty mix, type (academic and private practice), and location to obtain a substantial sample size for the evaluation.

II. Background

Imaging technology has dramatically advanced the power of medical diagnostics and provided critical tools for physicians to provide care through non-invasive approaches. For example, the use of advanced imaging techniques has the potential to improve patient care through earlier detection of disease that may reduce downstream morbidity and mortality. However, spending on advanced diagnostic imaging procedures has increased at a much faster rate than other Medicare expenses. In particular, the growth of advanced imaging procedures, such as MRI, CT, and nuclear medicine studies have been the most pronounced and accounted for close to 54 percent of total imaging expenditures in 2006 compared to 43 percent in 2000. (United States Government Accountability Office, GAO-08-452; June 2008)

Use and delivery of advanced imaging technology has undergone a number of changes. Imaging was once performed almost exclusively by radiologists, but cardiologists and other specialists now comprise a large and growing share of physicians furnishing imaging services. As the supply of imaging equipment has increased, imaging procedures have increasingly been performed in outpatient facilities and physician offices in addition to inpatient hospital settings. For example, between 1997 and 2006, the overall number of CT scanners grew by more than 50 percent, and the number of MRI scanners more than doubled. Some studies have found that utilization has grown more rapidly at facilities where referring physicians have an ownership interest (McKinsey & Company, 2007). The Medicare Payment Advisory Commission also has voiced concern over the three-fold difference in the utilization rate of Medicare-covered imaging procedures across the country.

Independent of this demonstration, CMS recently examined the trends in ionizing radiation exposure due to diagnostic imaging services among FFS Medicare beneficiaries from 1997 through 2007. Annual ionizing radiation exposure increased dramatically during this time. Thus, the potential for this demonstration to help reduce unnecessary ionizing radiation exposure has the most definite impact on the quality of care provided to Medicare beneficiaries.

Clinical guidelines provide physicians information on which imaging procedure is most likely to yield the most informative results, whether another modality is equally, or could be more, effective, and therefore more appropriate. The medical specialty society guidelines are developed and published to guide physicians in the appropriateness of treatment. Medical specialty society guidelines are critical for the practice of evidence-

based medicine and form a foundation of algorithms used by a DSS to guide appropriateness in ordering advanced diagnostic imaging services.

The demonstration focuses on the use of a DSS by physician practices to ensure that procedures ordered are appropriate and consistent with the medical specialty society guidelines. DSSs include point of order (POO) and point of service (POS) systems as defined by the authorizing statute. POO systems are computerized order-entry systems that require input of relevant supporting information at time of referral for advanced diagnostic imaging services and provide automated decision-support feedback to referring physicians regarding appropriateness of the order. A POS system uses an electronic or paper intake form that contains a physician certification that the data was confirmed with the beneficiary before the service was furnished, as well as the data necessary to determine appropriateness. The POS system also allows for electronic submission and provides feedback. This allows a physician practice that furnishes the imaging procedure the ability to participate in the demonstration without using a computerized order entry system. This allows, for example, a cardiology practice that may both order and furnish the service to participate in the demonstration. The DSS captures a physician attestation that the data to determine appropriateness and recommendations were reviewed by the physician and confirmed with the beneficiary.

The environmental scan also found that a DSS is commonly accessed through a Web portal or integrated directly into a provider's electronic medical record system. An algorithm based on the medical specialty society guidelines then presents the appropriateness of the procedure ordered and may offer alternative diagnostic procedure(s) for comparison.

Demonstration Information

A. Purpose

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. In addition, the demonstration relies on specified medical specialty society guidelines for these 11 procedures.

B. Procedure Selection and Corresponding Current Procedural Terminology (CPT) Codes

The following table (Exhibit 1) provides details of the selected tests for different images of the body and the corresponding CPT codes.

Exhibit 1: Demonstration Advanced Imaging Procedures List			
	Computed Tomography (CT) Codes	Magnetic Resonance Imaging (MRI) Codes	Nuclear Imaging (SPECT-MPI) Codes
Brain	70450; 70460; 70470	70551; 70552; 70553	-
Sinus	70486; 70487; 70488	-	-
Thorax	71250; 71260; 71270	-	-
Heart	-	-	78464; 78465
Abdomen	74150; 74160; 74170	-	-
Lumbar Spine	72131; 72132; 72133	72148; 72149; 72158	-
Pelvis	72192; 72193; 72194	-	-
Shoulder	-	73221; 73222; 73223	-
Knee	-	73721; 73722; 73723	-

C. Design

The demonstration requires: (1) an adequate sample of participating physicians from the major specialties responsible for ordering the 11 targeted advanced imaging procedures that are included in the demonstration; (2) a range of geographic areas; (3) a variety of demographic characteristics (such as urban, rural, and suburban); (4) a mix of practice settings (such as private and academic practices); and (5) the use of a DSS when ordering 1 of the 11 targeted advanced diagnostic imaging procedures for Medicare FFS beneficiaries.

1. Convener Responsibilities

CMS is seeking organizations to serve as convening entities. The responsibilities of the convener include, but are not limited to:

- Recruiting physician practices;
- Securing a DSS that meets the demonstration criteria specified in Section C. 4;
- Making the DSS available for use in the demonstration by participating physician practices;
- Ensuring the DSS incorporates the most current medical specialty society guidelines specified under this demonstration;
- Collecting data from physician practices via the DSS and submitting the data electronically to CMS;
- Distributing physician incentive payments and feedback reports to the participating physician practices;
- Assessing the satisfaction of Medicare patients receiving an advanced medical imaging service from a participating pracitece as well as the satisfaction of physicians participating in the demonstration;
- Defining a method and process for assessing patient and physician satisfactions with the DSS and results; and
- Serving as the point of contact with CMS for the demonstration.

Many types of organizations may be eligible to serve as conveners (e.g., medical societies, physician groups, integrated health care delivery systems, independent practice associations, information technology vendors, and radiology benefit managers), provided they are able to meet the requirements and perform the functions outlined in the solicitation. It is anticipated that up to 6 conveners may be selected, with each convener recruiting between 200 and 1,000 physicians. Under the demonstration, each physician practice can only participate with one convener and all physicians affiliated with a participating practice ordering advanced diagnostic imaging services must participate. Furthermore, all practices participating in the demonstration must use the DSS when ordering 1 of the 11 targeted advanced diagnostic imaging procedures for Medicare FFS beneficiaries.

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. The Secretary has chosen to use conveners as a vehicle to recruit physician practices for participation in the demonstration because it is expected that the likely applicants for the convener have well developed relationships (or the ability to establish) with a significant network of physicians that could be potential applicants for participation in the demonstration. Therefore, conveners would be highly effective at providing a robust panel of physicians that could satisfy the selection requirements outlined in the statute. Conveners must also disclose in the application whether the DSS may be retained by the participating practice after the demonstration is concluded and whether the DSS may be used to order items and services other than the subject imaging services

2. Physician Practice Characteristics

To be eligible to participate in the demonstration, a physician practice must participate in Medicare and as a practice must have ordered at least five claims for advanced imaging services for Medicare FFS beneficiaries in 2009. Only advanced imaging procedures from 1 or more of the 11 targeted procedures, which are the focus of the demonstration, count towards the minimum volume requirement.

3. Physician Practice Agreement

Physician practices must agree that all orders for the demonstration's 11 targeted advanced imaging procedures ordered for Medicare FFS beneficiaries will be entered into the DSS and that the data will be provided to CMS for purposes of the

demonstration. In order to facilitate physician practices' office workflow processes and avoid potential confusion, CMS anticipates that conveners will have their participating physicians use the DSS for all orders of MRI, CT, and nuclear medicine imaging procedures for Medicare FFS beneficiaries. 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).

For purposes of the demonstration, relationships between physicians, practices, and conveners must be exclusive. Practices and physicians may not participate in more than one convener's practice panel. The convener's proposal must include a completed list of participating physician practices (including the practice Tax Identification Number (TIN)), along with information on ownership of equipment for advanced imaging services.

4. Capabilities Specifications for Conveners and Physician Practices

Convener Requirements

Conveners must arrange for the availability of a DSS for their panel of physician practices participating in the demonstration. CMS will collect only data relevant to the 11 targeted advanced imaging procedures and guidelines identified for use in the demonstration. All guidelines must be transparent to the participating physician practices. The convener must recruit physician practices and make the DSS available to physician practices participating in the demonstration. For the duration of the demonstration period, the convener must ensure the DSS for advanced diagnostic imaging services is in agreement with the most current version available of the medical specialty society guidelines selected by the Secretary for use in the demonstration. A list of the medical specialty guidelines for the 11 targeted procedures is available on the MID Web site.

The demonstration employs a pre-post research design. During the first 6 months of the demonstration, CMS will collect baseline data on the appropriateness of orders for advanced diagnostic imaging services. For this period, the DSS will not include the assessment links for the participating physicians in order to capture the individual physician's ordering methods. After the initial testing and baseline data collection period, the remaining 18 months of the demonstration will be considered the intervention period during which assessment of appropriateness of orders will be presented at the time the order is entered into the DSS.

Conveners must adhere to the following requirements regarding the DSS structure and data capture for the 11 targeted advanced imaging procedures selected for study under this demonstration:

- The DSS must include decision support ordering for the 11 targeted procedures selected for study under this demonstration;

- The DSS must evaluate these procedures using the medical specialty society guidelines identified by CMS in the final terms and conditions (a list of guidelines is available at: http://www.cms.hhs.gov/DemoProjectsEvalRpts/downloads/Medicare_Imaging_Demonstration.pdf);
- Except for the (pre-intervention) baseline data collection period, systems must be transparent and show the source of the medical specialty society guidelines that underlies the DSS algorithm logic;
- The DSS must provide an assessment that conveys to the physician practice whether its orders for advanced diagnostic imaging services are: appropriate, inconclusive/uncertain, or not appropriate;
- The DSS must provide decision support feedback on appropriateness (including, if applicable, more appropriate alternative tests) to ordering physician practices at the time of order (except during the baseline data collection period);
- If medical specialty society guidelines do not provide guidance regarding a particular clinical scenario (e.g., possible diagnoses, signs/symptoms), the DSS needs to provide physician practices information indicating that appropriateness criteria do not address the clinical scenario;
- Test cases will be run to ensure comparability across all conveners' DSSs and CMS will require system modification if discrepancies are discovered;
- In the event that the medical specialty guidelines are updated, the DSS must be able to be modified and the convener must ensure that these modifications transpire;
- The DSS must have the capacity to distinguish between advanced diagnostic imaging services for the 11 targeted procedures and other imaging services;
- The DSS must comply with all applicable Federal and State privacy and security requirements for the transfer and storage of such data; and
- The DSS must be consistent with current Medicare policy (e.g., covered services).

The DSS must capture and provide the following data elements for each of the 11 targeted advanced diagnostic imaging procedures:

- Physician name;
- Practice TIN;
- Physician National Provider Identifier (NPI);
- Practice name and location;
- Patient name;
- Medicare Patient Health Insurance Claim Number (HICN);
- Patient demographics (e.g., date of birth, gender);
- Physician attestation that the data to determine appropriateness and recommendations were reviewed by the physician and confirmed with the beneficiary before the service was furnished;
- Date of data entry of order;
- Diagnosis and/or any relevant signs and/or symptoms and International Classification of Diseases 9th Edition (ICD-9) codes needed to support guideline-based algorithms;

- Procedure name and CPT code of imaging service originally ordered;
- Reason for ordering (e.g., initial diagnosis, follow-up study);
- Name and CPT code of imaging test ordered and performed (i.e., captures any changes in order after interaction with the DSS), or decision not to order a service;
- Appropriateness determination (appropriate/inappropriate/inconclusive) of original procedure ordered;
- Appropriateness determination (appropriate/inappropriate/inconclusive) of final procedure ordered;
- If an advanced imaging test is performed, the date of service of the test and the results of imaging procedure(s) administered (i.e., positive, negative, indeterminate); and
- The DSS must meet the technical specifications identified by CMS and defined in the final terms and conditions. (The specifications are available at http://www.cms.hhs.gov/DemoProjectsEvalRpts/downloads/Medicare_Imaging_Demonstration.pdf)

Conveners will be required, on a quarterly basis, to submit via a Secure File Transfer Protocol site the data in a format to be specified by CMS. A database on imaging orders at both the physician NPI level and the practice level will be constructed for quarterly reporting. Conveners should be prepared to address issues related to the performance standard of the completeness of reporting identified by CMS.

Conveners must provide feedback reports to participating physician practices that include a profile of the rate of compliance with the medical specialty guidelines by the physician and their peers participating in the demonstration along information on the utilization of services.

Physician Practice Requirements

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

- Use the demonstration DSS as described in Section II for the targeted advanced diagnostic imaging services ordered by the physician practice for Medicare FFS beneficiaries, and support electronic and secure data transmission to CMS through the convener. Physician practices may or may not directly enter data via Web portal or a DSS integrated into the provider's electronic health record system. However, all physicians in a participating practice must use a DSS (as described in Section II) and the convener must submit all orders for the 11 targeted procedures electronically to CMS.
- Receive feedback from the DSS 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 Section IV. C. Proposal Requirements.

- Participate in a physician practice satisfaction survey during the intervention period, if requested by CMS.

D. Participation Incentives

1. Physician Practices

Physician practices agreeing to participate in the demonstration are expected to continue participation for the 2-year demonstration period. Under the demonstration, participating physician practices will receive a financial incentive (to be determined by CMS) for reporting data to CMS (through the convener). The incentive 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 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 below (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.

Exhibit 2: Practice Ordering Volume Tiers/Incentive Payments

	Annual Medicare Test Ordering Volume (claims for 11 targeted advanced imaging procedures)	Annual Payment to Practice
Tier 1	Under 50	$1,000
Tier 2	51-100	$2,000
Tier 3	101-500	$4,000
Tier 4	501-1,000	$7,000
Tier 5	1,001 and up ($1,000 for each additional 1,000 tests up to a maximum of $20,000)	$8,000-20,000

After the completion of the baseline data collection, the practices will receive 50 percent of the first year's annual payment contingent on satisfying the COR performance threshold, as discussed below. The remaining amount of Year 1 annual payment will be paid after satisfactory submission of required data by the convener to CMS, including meeting COR performance requirements. For Year 2

of the demonstration, payment will be made in two payments based on quarterly submission of data, including satisfying Year 2 COR performance requirements.

Performance Standards for Physician Practices

For purposes of the demonstration, COR for physician practices consists of the following components related to Medicare FFS beneficiaries:

- A practice must submit a minimum of 1 DSS record for at least 1 of the 11 targeted advanced diagnostic imaging services semi-annually during the 2-year demonstration period to be eligible for payment.
- The DSS record must provide complete information in all required data fields.
- The participating physician practice has completed records in the DSS for all advanced diagnostic imaging procedures included in the demonstration that were ordered for Medicare FFS beneficiaries.
- The COR is calculated as a percentage of targeted procedures ordered by the practice as identified in Medicare claims that have been captured in the DSS record.
- The numerator will be the number of (the 11 targeted advanced diagnostic imaging) procedures selected for study under this demonstration with a DSS record. The denominator will be the number of Part B claims paid for the procedure (identified by CPT code) and ordered by the physician practice (identified by TIN and NPI).
- For Year 1 of the demonstration, the completeness of reporting performance measure is a minimum requirement of 80 percent; 90 percent for Year 2.

Participating practices will not be penalized for situations where there is a complete DSS record but for which no advanced imaging procedure was furnished (e.g., when a patient is not compliant or the DSS feedback is that no (demonstration) procedure is appropriate). Physicians will be presented feedback reports that will provide data on appropriateness of use of advanced diagnostic imaging services compared to other physicians and physician practices at the convener level and the demonstration level.

2. Conveners

CMS requires conveners applying for participation in the demonstration to propose a bid price for the operational and continual efforts required for the convener's administrative activities (such as reporting and payment distribution responsibilities) under the demonstration. CMS anticipates awarding up to six conveners depending upon budget limitations. Physician incentive payments are not included in this amount.

Payment to conveners will be contingent upon satisfying the following performance standards. Conveners will receive payments on a schedule similar to the semi-annual payment schedule for physician practices. In Year 1, 50 percent

of the annual payment will be paid after satisfactory reporting of baseline data collection, with the remaining amount of Year 1 annual payment paid after satisfactory reporting of required data, including meeting minimum Year 1 COR requirements for conveners as discussed below. For Year 2 of the demonstration, payment will be made in two payment shares based on quarterly submission of data, including satisfying minimum Year 2 COR requirements. Payments will be made to the conveners by CMS.

Performance Standards for Conveners

For purposes of the demonstration, completeness of reporting for conveners consists of the following components:

- Timely quarterly submission of data collected through the DSS used for the demonstration.
- The numerator will be the number of (the 11 targeted advanced diagnostic imaging) procedures selected for study under this demonstration with a DSS record. The denominator will be the number of Part B claims paid for the procedure (identified by CPT code) and ordered by all physicians in the convener's panel of participating practices (identified by TIN and NPI).
- For Year 1 of the demonstration, the completeness of reporting performance measure is a minimum requirement of 80 percent. For Year 2 of the demonstration, the completeness of reporting performance measure is a minimum requirement of 90 percent.

Conveners may not alter the incentive payment (determined by CMS) to the practices. A convener may not provide additional monetary payments to participating physician practices for participating in the demonstration. Conveners need to identify and explain in their proposals to CMS any additional non-monetary incentives offered to physician practices. For example, it may be possible for conveners to arrange with medical specialty societies to provide continuing medical education credit to participating physicians.

CMS may audit conveners to ensure compliance.

E. Program Monitoring

CMS will conduct program monitoring throughout the demonstration. Monitoring will include review of quarterly submission of required data specified in Section C.4. entered into the conveners' DSS by participating physician practices and submitted by the conveners to CMS. Data submitted by conveners to CMS will be used for: (1) assessing completeness of reporting by participating physician practices; and (2) preparing monitoring reports to physician practices on the appropriateness of orders for the 11 targeted advanced diagnostic imaging procedures included in the demonstration; and (3) payment determinations for physician practices and conveners.

Conveners must ensure the DSS is current with the medical specialty society clinical guidelines. Applicants will need to have a process for monitoring changes in medical specialty guidelines and provide an estimate of the time needed to perform a DSS update and test cases in the system for reliability if changes are significant (see Section C. on Proposal Requirements). During the initial 6-month baseline data collection, conveners must work with CMS to determine that data transmission functions properly.

F. Independent Evaluation

CMS will contract with an independent evaluator to assess the demonstration outcomes. Conveners and participating physician practices must provide all necessary demonstration information to support the evaluation. Data to be provided to the evaluator will include, but is not limited to, the data discussed in Section C.4.

Conveners must agree to site visits by CMS and its contractors.

III. Provision of this Solicitation

A. Purpose

This solicitation requests proposals for participation in the MID. The demonstration will test whether the use of a DSS can improve quality of care and reduce unnecessary radiation exposure and utilization by promoting appropriate ordering of advanced imaging services. Physician practices will receive feedback on the degree of appropriateness relative to the specified medical specialty society guidelines used under the demonstration. The demonstration makes no changes to Medicare coverage or payment policies. The demonstration does not involve prior authorization and only involves the Medicare FFS program.

B. Selection Process

A review panel convened by CMS will evaluate all submitted proposals based on the proposal criteria listed in this section of the solicitation. Based on the review panel recommendations, CMS may seek additional information from applicants.

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 a waiver is necessary to carry out the demonstration project.

C. Proposal Requirements

Applicants must submit their applications in the standard format outlined in CMS' Medicare Waiver Demonstration Application and MID solicitation in order to be

considered for review by the technical review panel. Applications not received in this format will not be considered for review. Proposals should be mailed or delivered to the following address:

Linda R. Lebovic
Project Officer
Office of Research, Development, and Information
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Mail Stop: C4-17-27
Baltimore, Maryland 21244-1850

For further information on proposal submission requirements, contact Linda R. Lebovic at (410) 786-3402 or by e-mail at ImagingDemo135b@cms.hhs.gov.

The Medicare Waiver Demonstration Application is available at: http://www.cms.hhs.gov/cmsforms/downloads/cms10069.pdf. The MID solicitation and related medical specialty guidelines are available on CMS' Web site at: http://www.cms.hhs.gov/DemoProjectsEvalRpts/downloads/Medicare_Imaging_Demonstration.pdf.

Proposals will be considered timely if they are received no later than **September 21, 2010**. Only proposals that are considered "timely" will be reviewed and considered by the technical review panel. Proposals must be typed for clarity and must not exceed 40 double-spaced pages, exclusive of the cover letter, executive summary, resumes, forms, and supporting documentation. An unbound original and two copies, plus an electronic copy or CD-ROM must be submitted.

Applicants may, but are not required to, submit a total of 10 copies to assure that each reviewer receives a proposal in the manner intended by the applicant (e.g., collated, tabulated color copies). Hard copies and electronic copies must be identical. Applicants must designate one copy as the official proposal.

At a minimum, applicants should ensure that their proposals and supplemental materials include the information requested below by section of the proposal:

1. **Cover Letter**: Please be sure to identify the demonstration, applicant convener, geographic location proposed for the demonstration, contact person, and contact information.

2. **Medicare Waiver Demonstration Application**: Complete, sign, date, and return the Data Sheet found at the beginning of the application. The application is available at http://www.cms.hhs.gov/cmsforms/downloads/cms10069.pdf.

3. **Executive Summary**: Provide a brief summary of the key elements of the proposal.

4. **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 at: http://www.cms.hhs.gov/DemoProjectsEvalRpts/downloads/Medicare_Imaging_Demonstration.pdf) ;
   - 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.

5. **Demonstration Design**: Applicants should describe how the demonstration design addresses, but is not limited to the following:

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

6. **Organizational Structure and Capabilities:** The proposal should describe how the applicant will organize and manage the project, describe the sequence of tasks and timeframes slated for completion of critical milestones, and describe management controls and coordination mechanisms that will be utilized to ensure the timely and successful conduct of this project. Potential problems that may be encountered in the process of implementing the project should also be addressed. The proposal should address each but is not limited to the following:

   - Indicate the convener's capacity and capability to effectively conduct this project. Discuss availability and access to resources and facilities, including staff, computer systems, and technical equipment;
   - Describe the governing body that will oversee the operation of the demonstration and provide detail on how the oversight will be conducted;

- Identify and describe the DSS and its design features, functionality, technical specifications, system requirements, physician practice outreach and education. Specifically explain how the DSS meets 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;
- Indicate assumptions regarding turnover in the physician and practice panel, and how the convener expects to handle practice drop-out and turnover in physicians associated with respective practices in order to maintain an adequate sample of physicians for the demonstration; and
- Demonstrate widespread support by all physician practices and other personnel as applicable, including cooperation with reporting and survey response by including signed agreements or letters of intent with physician practices and their physicians for demonstration participation.

7. **Performance Results**: The proposal should describe systems and processes for monitoring clinical, financial, and operational performance. The description should include but is not limited to:

   - How the applicant will support semi-annual feedback reports to physician practices, including proposed report examples of the data to be provided at physician, practice, and convener levels;
   - Indicate the quality assurance strategy, including processes to be used to monitor changes to the medical specialty society guidelines used in this demonstration, the time needed to update the DSS if guidelines change, and to test cases if changes are significant; and
   - Describe how the convener will monitor physician practice compliance with the terms and conditions of the demonstration.

8. **Proposed Budget and Incentive Payments:** 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.

9. **Demonstration Implementation Plan**: Describe a plan that includes, but is not limited to, the following elements:

   - Identify the proposed project manager or liaison to CMS for the demonstration. Applicants must describe plans to report demonstration progress to the CMS project officer;
   - Identify key personnel and describe the functions and duties of each. Include a brief description of relevant training, experience, publications, and availability of key personnel for the duration of the project. Include staff resumes of key personnel; and
   - Indicate the approach and timeline needed to implement the DSS in compliance with the demonstration's requirements, including transparency of the medical specialty society guidelines used in this demonstration and baseline data collection, and intervention period. Provide a detailed schedule with timeframes for all essential tasks.

10. **Supplemental Materials**: Include copies of supporting materials requested or referenced throughout the application.

D. Evaluation Criteria

The applicant must meet the design requirements as described above and will be evaluated using the following criteria:

1. **<u>Organizational Structure and Capabilities</u>** (30 points out of 100 points)

   - Convener has widespread physician practice participation that meets the minimum ordering requirements and support for the project, and has included all necessary documentation.
   - Convener has in place plans for maintaining the minimum number of participating physicians through the demonstration period, including a representative mix of participating physicians and practices (a range of medical specialty, geographic, and demographic characteristics).
   - Convener can make available a POO and/or POS DSS to participating physician practices that meets the requirements of the demonstration, and has in place mechanisms to educate practices on its use and demonstration requirements.
   - Convener has the ability to monitor participating physician practices' compliance with pay for reporting requirements.
   - Convener can demonstrate the ability to successfully implement and operate the proposed program, including electronic capabilities to use a POO and/or POS DSS to collect data from practices and report it to CMS and its contractors in a form and manner that meet the demonstration requirements and specifications, and all applicable Federal and State privacy and security requirements.

2. **Budget** (20 points out of 100 points)

    - Convener budget, exclusive of physician payments, must provide best value for achieving the demonstration's goals and objectives given the available demonstration funding.

3. **Quality Improvement and Appropriateness** (20 points out of 100 points)

    - DSS provides immediate feedback on the ordering of all 11 targeted advanced diagnostic imaging procedures.
    - DSS guidelines are consistent with identified medical specialty society guidelines, which have been selected by the Secretary for use in this demonstration and are transparent, including the source of the clinical guidelines to the physician at the time of DSS use.
    - Convener has mechanism in place to provide the physician feedback on appropriateness and utilization rates, as well as image results at the physician, practice, and convener levels.
    - Convener has a method to assess the satisfaction of Medicare patients receiving an advanced medical imaging service from a participating pracitece as well as the satisfaction of physicians participating in the demonstration, and a process for assessing patient and physician satisfactions with the DSS and results.

4. **MID Implementation Plan** (30 points out of 100 points)

    - Convener has a plan for addressing key demonstration design elements for participating practices, the DSS, data flow, and project management and evaluation.
    - Convener has sufficient staff, systems, and other resources in place to organize, plan, and implement the demonstration.
    - Convener has effective management and organizational structure in place for use of the DSS to affect the advanced diagnostic imaging ordering behavior of physicians.
    - Convener agrees to cooperate with CMS design, implementation, and evaluation contractors.

E. Final Selection

A review panel will provide recommendations to CMS regarding the final selection of participants from among the most highly qualified candidates. Conveners will be selected based on meeting the requirements outlined in this solicitation, including organizational structure, operational feasibility, soundness of demonstration design, and representativeness of the physician practices panel, including geographic and demographic characteristics.

CMS will use its authority to waive the application of certain fraud, waste, and abuse laws, if at all, only after evaluating the provisions of the proposals on a case-by-case basis.

Award is contingent on the acceptance of CMS demonstration terms and conditions prior to the start of the demonstration.