KING & SPALDING

Health Headlines

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CMS Announces it is Accepting Applications for a "Bundled Payment for Care Improvement Initiative" – On August 23, 2011, the Centers for Medicare & Medicaid Services (CMS) announced that is was seeking applications for participation in one or more of its initial four models in the Bundled Payments for Care Improvement initiative (Bundled Payment Initiative) beginning in 2012. Section 3023 of the Patient Protection and Affordable Care Act (PPACA) requires CMS to establish, by January 1, 2013, a pilot program for integrated care during an episode of care furnished to Medicare beneficiaries around a hospitalization "in order to improve the coordination, quality, and efficiency of health care services."

The Bundled Payment Initiative is being launched by the CMS "Innovation Center" (a creation of PPACA), and seeks to test payment models centered around hospital admissions that would achieve these statutory objectives. There are four models being tested by the program:

- **Model 1**: Retrospective payment models around the acute inpatient hospital stay only.
- **Model 2**: Retrospective bundled payment models for hospitals, physicians, and post-acute care providers for an episode of care consisting of an inpatient hospitals stay followed by post-acute care.
- **Model 3**: Retrospective bundled payment models for post-acute care where the episode of care does not include the acute inpatient hospital stay.
- **Model 4**: Prospectively administered bundled payment models for the acute inpatient hospital stay only, such as prospective bundled payment for hospitals and physicians for an inpatient hospital stay.

CMS has invited organizations to submit proposals that define episodes of care in one or more of these four models, and requests that the proposals "demonstrate care improvement processes and enhancements such as reengineered care pathways using evidenced based medicine, standardized care using checklists, and care coordination." For each model, CMS has provided some broad parameters, such as a minimal Medicare saving rates, but many aspects of the initiative are opened-ended and subject to the provider's proposal. Providers, for example, will have flexibility to determine which episodes of care and which services will be bundled together and will propose a price for those services. Under Models 2 through 4, participants will be able to request Medicare claims data to assist them in arriving at a definition of episode of care, a payment rate for the bundled services, etc.

According to the CMS Fact Sheet, applicants would propose the target price for a defined episode of care in the three retrospective models, which would be set by applying a discount to total costs for a similar episode of care as determined from historical data. Participants in these models would be paid for their services under the original Medicare fee-for-service (FFS) system, but at a negotiated discount. At the end of the episode, the total payments would be compared with the target price. Participating providers may then be able to share in those savings.

The prospective model (Model 4), would involve CMS making a single, prospectively determined bundled payment to the

hospital that would encompass all services furnished during the inpatient stay by the hospital, physicians and other practitioners. Physicians and other practitioners would submit "no-pay" claims to Medicare and would be paid by the hospital out of the bundled payment. CMS specifically indicated that the proposals for participation under any of the models "may include gain sharing arrangements."

It is clear that both Congress and CMS consider bundled payment initiatives as key to controlling rising health care costs, while at the same time, at least in theory, improving the quality of outcomes. Indeed, in its press release, CMS points to its Heart Bypass Center Demonstration Project from 1991-1996 (involving ten hospitals, although only seven hospitals participated for all five years of the project), which boasted $42.3 million in cost savings to the Medicare program (a ten percent reduction in expected costs). In addition, the demonstration project also saved $7.9 million in copayments and reduced hospital mortality rates. Thus, the Bundled Payment Initiative is likely an omen of the future of Medicare reimbursement and presents an opportunity for providers to take part in the development of these future payment models.

The non-binding letter of intent and application for Model 1 are due by September 22, 2011 and October 21, 2011, respectively. The non-binding letter of intent and application for Models 2 through 4 are due by November 4, 2011 and March 15, 2012, respectively. In addition, to receive Medicare claims data, participants in Models 2 through 4 must submit a "research request packet" and data use agreement when they submit their letter of intent. CMS's Fact Sheet about the initiative is available **here** and the Department of Health and Human Services' news release is available **here**. More detailed program and application information is available **here**.

King & Spalding will host a Roundtable designed to address several issues relating to the Bundled Payment Initiative. For more specifics on this Roundtable discussion and information on how to sign up to participate, please refer to the announcement at the end of this publication.

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HHS Releases Final Rule Updating Conflict of Interest Standards for Federally Supported Research – On August 23, 2011, the Department of Health and Human Services (HHS) issued a Final Rule updating conflict of interest standards for institutions and investigators seeking or receiving Public Health Service (PHS) funding via federal grant, cooperative agreement, or contract. The Final Rule modifies and supplements regulations first implemented in 1995, titled "Responsibility of Applicants for Promoting Objectivity in Research for which Public Health Service Funding is Sought" and "Responsible Prospective Contractors," codified at 42 C.F.R. Part 50, Subpart F and 45 C.F.R. Part 94, respectively.

The National Institutes of Health (NIH) issued a press release detailing some of the major changes to the regulations, which include: revising the definition of significant financial interest (SFI), expanding mandatory investigator disclosure, increasing the amount of information reported to the PHS Awarding Component, making accessible to the public certain conflict of interest information, and mandating certain investigator training. For example, the new regulations:

- Require investigators to disclose to their institutions all SFIs related to their institutional responsibilities, in addition to their research responsibilities.
- Lower the monetary threshold at which SFIs require disclosure, generally from $10,000 to $5,000.
- Require institutions to report to the PHS Awarding Component additional information on identified financial conflicts of interest and the manner in which they are being managed.
- Require institutions to make certain information concerning identified SFIs accessible to the public via website or by written response within five business days of a request.
- Require investigators to complete training related to the regulations and their institution's financial conflict of interest policy.

Notably, the Final Rule modified a provision featured in the Proposed Rule (75 Fed. Reg. 28668, May 21, 2010), which would have required all institutions to post investigators' SFIs on a publicly accessible website. The Final Rule allows institutions to forgo online publication and requires only that institutions respond to certain individual requests for SFI

information within five business days.

Any institution applying for or receiving PHS funding must be compliant with the new regulations no later than August 24, 2012 or immediately upon making its institutional Financial Conflict of Interest policy publicly available, as required by the new regulations. Until then, institutions and investigators must continue to remain compliant with the 1995 regulations.

The Final Rule can be found **here**. The NIH press release regarding the updated conflict of interest rules may be read **here**. U.S. Senator Charles Grassley released a statement on August 23, 2011 responding to the publication of the Final Rule; Senator Grassley's press release is available **here**.

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Prior Version of 855 Forms Accepted Through October 2011 – The Centers for Medicare and Medicaid Services (CMS) has announced that although providers and suppliers should begin using the recently revised versions of the Medicare Provider-Supplier Enrollment Applications (CMS-855) now, the 2008 versions may be used through *October 2011*. Providers and suppliers enrolling for the sole purpose to order and refer must use the *new* CMS-855O form immediately. The revised CMS-855A, 855B, 855I, 855S, and 855R forms, as well as the new 855O, are available **here**.

The changes that providers will see to the revised 855A include the following:

- A provider that is a physician-owned hospital must report that physician ownership and must complete a separate Attachment to the 855A that requires information to be completed for every organization and individual that has *any* percentage of ownership or investment interest in the provider.
- Providers must now list cost report year end date.
- Section 5 ("Ownership Interest and/or Managing Control Information (Organizations)") now requires an organizational diagram identifying all of the entities listed in the section and their relationships with the provider and with each other. If the provider is a skilled nursing facility (SNF), a diagram must be provided that identifies the organizational structures of all of the SNF's owners, including owners that were not required to be listed in Section 5 or in Section 6.
- Providers must list the exact percentage of ownership or control interest in the provider that the owning/managing organizations listed in Section 5 have.
- Section 5 also specifically states that "all entities with at least a five percent mortgage, deed of trust, or other security interest in the provider" must be reported.
- Section 6 ("Ownership Interest and/or Managing Control Information (Individuals)") also now requires that percentage of interest in the provider be reported, as well as the listed individual's place of birth.
- If any of the organizations or individuals in Sections 5 or 6, respectively, provide contracted services to the provider, the types of services furnished must be described.
- Whereas the prior version of the 855A required that any organization or individual that had a partnership interest in the provider, regardless of the percentage of ownership, be listed in Section 5 or 6, the revised 855A specifies that for *limited partnerships*, limited partners must be reported only if their interest in the limited partnership is at least ten percent.

Revisions to the 855R, 855I, and 855S are less extensive, and the revised CMS 855B does not include the same extensive changes and instructions to the ownership and managing control sections as with the revised 855A. The changes that suppliers will see to the revised 855B include the following:

- Advanced Diagnostic Imaging (ADI) suppliers must provide the name of the Accrediting Organization that accredited the supplier's ADI Modality. This change is also included in the revised 855I.
- Unlike the revised 855A, the revised 855B still requires suppliers to list any organization or individual with a partnership interest in the supplier, regardless of the percentage of ownership the partner has.

- Individuals listed in Section 6 must also include their state and country of birth.

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Joint Commission Issues Alert on the Radiation Risks of Diagnostic Imaging – On August 24, 2011, the Joint Commission issued a Sentinel Event Alert (the "Alert") regarding the risks associated with diagnostic imaging. The Alert notes that although there is disagreement among experts about the risk of cancer from diagnostic imaging, there is agreement that measures should be taken to eliminate unnecessary exposure to radiation. Providers are urged to carefully consider the medical necessity of a given level of radiation exposure. The Alert notes that as a result of the risks associated with diagnostic imaging, the Centers for Medicare and Medicaid Services (CMS) will require the accreditation of freestanding imaging facilities providing advanced imaging services beginning January 1, 2012. The Joint Commission also cites to legislation enacted by the state of California that requires documentation of the radiation dose received by the patient for each CT examination.

In May 2011, the American College of Radiology (ACR) launched a National Radiology Data Registry (NRDR). The NRDR is a warehouse of ACR registry databases that compares radiology facilities regionally and nationwide according to facility type. The NRDR allows facilities to compare their results to regional and national benchmarks for quality improvement purposes.

The Joint Commission's Alert states that healthcare organizations can reduce risks due to avoidable diagnostic radiation by, among other things, raising awareness among staff and patients of the potential risks, providing the right test and dose through effective processes, safe technology and promoting a culture of safety. The specific actions suggested by the Joint Commission include the following:

- Use other imaging techniques, such as ultrasound or MRI, whenever these tests will produce the required diagnostic information at a similar quality level;
- Adhere to ALARA guidelines as required by the Nuclear Regulatory Commission. The ALARA acronym stands for "as low as reasonably achievable"—making sure doses are as low as possible while achieving the purposes of the study;
- Radiologists should confirm that the proper dosing protocol is in place for the patient being treated;
- Ensure all physicians and technologists who prescribe diagnostic radiation or use diagnostic radiation equipment receive dosing education and are trained on the specific model of equipment being used;
- Have a qualified medical physicist test all diagnostic imaging equipment initially and at least annually or every two years thereafter to assure proper installation and calibration, and review scanning protocols and doses; and
- Use the following Joint Commission standards to support the use of safe and effective diagnostic radiation: LD.03.01.01, LD.03.04.01, LD.03.05.01, LD.03.06.01.

According to the Alert, the Joint Commission endorses the creation of a national registry to track radiation doses, encourages manufacturers to incorporate dosage safeguards into diagnostic imaging equipment and supports stricter regulations designed to eliminate avoidable imaging and monitor the appropriateness of self-referred imaging studies.

The Joint Commission Alert is available by clicking **here**.

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King & Spalding Upcoming Roundtable on the Medicare Bundled Payments Initiative – On Monday, September 12, 2011, the firm will host a Roundtable focused on the Medicare Bundled Payments for Care Improvement initiative, and the Request for Applications released on August 23 relating to the four initial bundled payment models. The initiative is a significant step in the implementation of payment reforms authorized by the Patient Protection and Affordable Care Act (PPACA). The initiative is important because it will remove regulatory barriers to realigning incentives to enhance quality and efficiency, and may result in enhanced overall payments to successful participants.

Leading the Roundtable will be **Dennis Barry**, **Glen Reed** and **Greg Etzel**, of our Washington, D.C., Atlanta and

Houston offices, respectively. The Roundtable will take place at the Atlanta office from 1:00 PM to 2:30 PM Eastern time, with lunch available for in-person attendees from 12:00 PM to 1:00 PM. You can read additional information on the agenda and register to attend the Roundtable by clicking **here**.

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