Compliance Advisory:

The CMS Clinical Research Policy

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Enhancing Compliance Safeguards in Anticipation of the October CMS Clinical Research Policy

Providers conducting research studies should begin preparing for the release of the Medicare Program's new Clinical Research Policy (CRP), expected by October 17, 2007. The new CRP will likely have significant effects on provider compliance programs and is currently expected to become effective immediately upon release, without any transition period.

At an August 7 Open Door Forum, the Centers for Medicare & Medicaid Services (CMS) provided important clarifications to the proposed CRP that the agency released July 19, 2007. Standing out among the clarifications is that the current Clinical Trial Policy (CTP) will continue to be the coverage rule for any research study that enrolls a patient before October 17, 2007. Any study that enrolls its first patient on October 17 or after, will need to apply the new CRP rule for coverage. CMS indicated that providers will not be able to choose between the CTP or CRP for coverage of existing studies. As long as the study has enrolled a patient at any study site, items and services will need to meet the current CTP rules and not have the option of using the new CRP rules.

> The revised CTP keeps the entire conceptual framework of the original rule which allows Medicare to cover "routine costs" during "qualifying clinical trials."

The proposed CRP will be issued in final form by October 17, 2007 and will be effective that date. CMS officials stated that under the statutory process for reconsidering national coverage determinations, the agency does not believe it has authority to offer a transition period and that the coverage rule will be effective immediately.

Summary of Impact

The continued relevance of the CTP, even after the CRP is issued, and the immediately effective nature of the CRP has the following practical impacts for providers:

- Two coverage rules will exist for the next several years. Determining which coverage rule will depend upon when the study enrolls its first patient.
- CMS is emphasizing that all claims for services during research studies should be analyzed under the appropriate coverage policy. CMS expects existing studies to be scrutinized for coverage and not merely new studies.
- Providers should begin planning their operational response to the new CRP, particularly with respect to how to deal with any existing research studies that have not been incorporated into the compliance program process or have not been subject to coverage analyses and compliance safeguard review.
- Although the specifics of the CRP will not be released until mid-October, compliance program structural planning should begin immediately so that providers do not fall farther behind compliance expectations. It is unlikely that providers that have not instituted compliance safeguards can be ready by October 17 to handle immediately effective new coverage rules, but a provider can significantly decrease risks of being viewed as inactive if the provider develops a plan to come into compliance.

- Assembling databases of existing studies and tracking new studies and new enrollees will become central operational features for successful compliance safeguards.

This is CMS's second attempt at revising the Clinical Trials NCD that was originally issued in September 2000. On July 9, 2007 CMS issued a slightly modified CTP that essentially maintained the 2000 CTP as status quo while a new attempt at issuing a reformed CRP was launched.

Proposed CRP Changes from the Current CTP

The proposed CRP maintains the conceptual framework of the current CTP in that Medicare coverage is based on a research study first meeting the standards of a "qualifying clinical research study." If a study is a qualifying clinical research study, then Medicare will cover items and services that are "usual patient care" if Medicare covers the item or service outside the study. The standards of a qualifying clinical research study are substantially similar to the standards set out in the proposed CRP from earlier this year, however, the current proposal contains a different articulation of the therapeutic intent standard. The proposed CRP removes the concept of "deemed studies" and requires that the sponsor or investigator self-certify that the study meets all thirteen standards. This self-certification process is a method by which CMS will allow many investigator-initiated studies to continue to be covered.

Highlights of Open Door Forum Clarifications

- The following are highlights of the policy points emphasized by CMS at the August Open Door Forum. Due to the short amount of time before the CRP is finalized, it is highly likely that the intentions and goals CMS articulated at the Forum will be finalized into the CRP.

- One of the standards that a study must meet in order to qualify for coverage is that its "principal purpose" must be to investigate health outcomes. An additional standard allows coverage if any of the objectives measures health outcomes and it does not matter whether the objective is primary or secondary if the study is investigating a life-threatening condition. CMS acknowledged that the wording of the proposed CRP's therapeutic intent standard continues to need revision in order to adequately meet this goal.

- CMS stated that it will not be clarifying any ambiguous language in the current CTP, even though the current CTP will continue to be the coverage rule for any existing studies. However, CMS will allow providers to consult their local Medicare medical director for clarifications and that the local Medicare medical director will have authority to provide local interpretation of the CTP.

- CMS clarified that a study only needs to be certified once as a qualifying clinical research study and then all providers can rely on CMS's acceptance of that certification. The responsibility for certifying the study will reside with the sponsor or the principal investigator.

- All research studies must meet the CRP rules if the research study involves prospective clinical interaction, anticipates collecting data from clinical interaction, and requires an informed consent. This includes prospective data registry trials. In a "prospective study," the need for an informed consent will be a trigger for needing to follow the CRP.

- If a study does not meet all of the standards of the CRP, then no items or services required by the study can be billed to Medicare. However, if complications arise from the study, CMS will cover treatment of complications without respect to whether the study is or is not a qualifying research study.

- When a self-certification letter is sent to CMS, the agency will review the letter for completeness but will not audit the accuracy of the information set out in the certification letter. CMS anticipates developing a template letter that will assist sponsors and investigators in the self-certification process.

- CMS clarified that under the CRP, all clinical research studies stand on equal footing and coverage is not dependent upon whether the study is funded by government agencies or is privately funded. Government funded studies will not be given any special pass to automatically be deemed as meeting the qualifying research study standards.

How Will the Proposed CRP Affect Providers?

If the CRP is adopted as it has been proposed or with the policy goals articulated by CMS at the August Forum, the following will be some of the impacts on health care providers that conduct clinical research:

- Providers will need to conduct coverage analyses under two different Medicare coverage rules depending upon when the study has begun to enroll patients. If the study has enrolled a patient before October 17, 2007 at any of the study sites, then the provider must use the current CTP for the remaining

The following are the most important points of the CRP that are proposed to be changed in October:

- Either the CTP or the CRP will apply to a research study. Providers must determine which coverage rule applies for every study before claims for services can be billed.
- The concept of a Qualifying Clinical Trial under the current CTP will be called a "Qualifying Clinical Research Study" under the CRP.
- Device studies with Investigational Device Exemptions should continue to follow the device trial regulations. All other research studies must apply the CTP or CRP to obtain coverage for study-required items and services.
- If a study is not a "qualifying clinical trial" under the CTP or a "qualifying clinical research study" under the CRP, then no study-required services will be billable to the Medicare program.
- The concept of "routine costs" under the current CTP will be called "usual patient care" under the CRP and will include the investigational item or service if Medicare normally pays for the item or service outside a research study.
- CMS will refer to organized research that is subject to the policy as "clinical research studies" rather than "clinical trials" to ensure there is clarity that the policy addresses items and services in any research study.
- In order to be a qualifying clinical research study, the research must meet 13 "standards." The standards replace the 10 "criteria" of a qualifying clinical trial under the current CTP.
- Self-certification only needs to occur once for a study, including multi-site studies. If a study has already been self-certified and has been posted on the CMS website, then the provider will be able to rely on the study as being a qualifying research study under the CRP.
- Providers or sponsors that submit erroneous self-certifications could find themselves liable for billing activities that have relied on their self-certifications.
- The therapeutic intent standard will be expanded under the CRP to allow studies to be considered to have therapeutic intent if any of the protocol's objectives include evaluation of health outcomes as long as the study is treating a life-threatening condition. If the study is not investigating a life-threatening condition, then therapeutic benefit must be one of the protocol's primary objective in order to obtain coverage.

life of the study. If the study begins enrollment on or after October 17, 2007, then the study will need to meet the CRP coverage rules.

- Providers will need to educate appropriate personnel on both the current CTP and the new CRP even after the CRP goes into effect.
- Providers will need to develop databases and institute compliance safeguards (e.g., performing a coverage analysis) for any research study that involves clinical interaction with a patient and requires an informed consent, even if all items and services during the research study are conventional care and would not be different outside the study. As a practical matter, this means that the CRP rules affect virtually all medical research studies that involve active interaction with human subjects.
- Although providers that are merely a study site (and not the lead site) will be able to rely on CMS accepting a single self-certification for the research study by the sponsor or lead principal investigator, providers must still follow local coverage determinations (LCDs) that may be in effect in the provider's region. National acceptance of self-certification does not disturb the local Medicare contractor's jurisdiction over determining whether the specific items and services during the study are reasonable and necessary and should or should not be covered.
- If a provider is the lead research site for a study, that provider will need to inform its sub-sites whether any patients have been enrolled in the study as of October 17 in order for the sub-sites to know whether to follow the CTP or the CRP rules for

coverage.

- Investigator-initiated studies will need to be self-certified and the principal investigators will need to be trained on the CRP standards that the investigator will certify.

Self-Certification Compliance Risks

While the self-certification process allows Medicare to cover considerably more research studies than under the current CTP (and much more than the proposed CRP from earlier this year that was not adopted), providers should approach the certification process with great care. When an investigator signs the self-certification letter, the investigator will be making representations to the federal government that the statements are true and accurate. This not only means that the government could hold the individual investigator personally accountable for making false statements if the letter is inaccurate, but many other providers will be relying on the investigator's certification.

While CMS was clear at the August 7 meeting that a provider can rely on a CMS approved certification of a study (which will be posted on the CMS website), the ramifications are large for an investigator that files a false statement. Providers will need to carefully educate their investigators who file self-certifications and will need to develop compliance controls, such as auditing, to ensure that the investigators are adequately certifying the standards. Because CMS will only be checking the initial self-certification letters for completeness and not subsequent accuracy, the veracity of the self-certification may not be reviewed or audited for a considerable time period.

What Can Providers do to Prepare for the CRP?

The following are five actions that a provider can take prior to the issuance of the October CRP in order to prepare for CRP coverage changes and increased government and industry scrutiny of research billing:

1. Begin assembling databases of existing studies and currently enrolled patients. If this cannot be achieved expeditiously, then providers should consider instituting a plan and timeline for accumulating the information.

2. Develop a plan to require any new study to be reviewed for Medicare coverage by a central source at the provider (or under common processes) in order to establish the study's status as qualifying for Medicare coverage. Ideally this review would occur before the provider agrees to conduct the study and before negotiations over the study budget is concluded.

3. The provider should identify a leader or coordinator of its research billing compliance initiative, and if need be, assemble a committee that will manage the initiative.

4. The provider should begin familiarizing itself with the structure and concepts of the current CTP rules, if it has not already done so. While the specifics of the final CRP will not be released until mid-October 2007, the current CTP will remain the rule for a vast number of research studies for a considerable period of time and the basic structure of the CRP will be based on the concepts of the CTP.

5. Develop a plan now on how to communicate to medical staff the final CRP rules once they are released. While government expectation is that all claims for items and services during research studies will comply with Medicare coverage rules, at a minimum, a provider should prepare to comply with whatever rules are in the CRP for new studies as of the CRP release date.

The period leading up to the issuance of the final CRP is a golden moment for providers to develop a plan to roll out going-forward controls minimally for new studies (even if the roll-out initially involves merely education and collection of information on studies and enrollees).

If you have any questions about clinical research compliance, please contact:

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