Compliance Advisory:

New CMS Research Modifier Rules

MEADE & ROACH LLP

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CMS to Begin Collecting Data on Clinical Research Billing

New Modifiers Required on Research Study-related Claims

The Centers for Medicare & Medicaid Services (CMS) will start collecting data on providers' clinical research services billing in April 2008. Local Medicare contractors for Part A and Part B are now required to submit data to CMS that will help the government track what clinical research services providers are billing to Medicare. The data tracking will be based on the new Q0 and Q1 modifiers and the voluntary placement of the clinical trial registration number on the claim form.

Under the new modifier rules, providers will need to sort all protocol-required services into a Q0 or Q1 service. Providers should consider incorporating the Q0 and Q1 identification into their Medicare Coverage Analysis process.

On January 18, 2008, CMS released two transmittals requiring changes to the Medicare Claims Processing Manual and to Medicare contractors' claims processing systems. The changes were made retroactive to January 1, 2008. CMS eliminated modifiers QV, QR and QA and replaced them with two modifiers, Q0 and Q1, which apply for all clinical research studies. The modifiers will no longer be different between drug trials and device trials.

A claim that contains an "investigational clinical service" must use the Q0 modifier on the HCFA 1450 form (for facilities) or HCFA 1500 form (for physicians). A claim that contains a "routine clinical service" must use the Q1 modifier on the forms.

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The change in the modifier rules is significant because it represents a pivotal step by CMS to understand what investigational and routine services are being billed during specific clinical research studies. The previous modifier rules were rarely enforced and contained a complicated schema of use depending on the type of research study. This recent change unifies the modifier rules, and it allows CMS to undertake significant data-mining to compare different institutions' billing practices for the same research study. While the modifiers continue to be revenue neutral, neither adding nor subtracting reimbursement for research study-related services, the new rules will be a powerful mechanism for the government's billing compliance enforcement.

Clinical Trial Registration Number

The CMS transmittals also require Medicare contractors to modify their systems to allow providers to submit the clinical trial registration number on the claim form. A unique number is assigned to a clinical research study that is registered at the government website clinicaltrials.gov. Each registered research study is given a unique control number that can be used at all study sites. Placing the clinical trial registration number on the claim form is voluntary.

CMS is clear in its January 18, 2008 transmittal that "CMS will use this number to identify all items and

services provided to beneficiaries during their participation in a clinical trial." Providers should expect that in the future CMS will require this number to be placed on all claims.

To support the monitoring of clinical research billing, CMS is requiring Medicare contractors to transmit the clinical trial number and associated claim information to the Medicare "common working file" maintained by CMS. The CMS common working file is a database that tracks clinical and claims information for each Medicare patient, regardless of where or from whom the patient has received services. In a sense, the common working file contains each Medicare patient's master file of data.

The January 2008 instructions from CMS require that the common working file "shall generate one monthly report" of research billing information and "transmit it to the CMS data center." These reports will begin in April 2008.

What Can CMS Learn From the Data?

Although plans for the new clinical research data gathering by CMS is not known, an extraordinary amount of information will be at CMS's fingertips. Since the common working file contains most of the claims data for a Medicare patient, it will be an easy process for CMS (or OIG) to run reports comparing the billing practices of different sites working on the same study. CMS will also be able to easily examine how different providers are billing for the same research patient.

The new data collection efforts by CMS make coordination among providers and between study sites critical. Two examples illustrate this point:

- Patient Jones is enrolled in a research study and the hospital identifies the patient on the claim form as participating in Study 123. The government can easily look to see if the physician has also identified Patient Jones as enrolled in a research study, what services the physician has or has not billed and whether the physician has assigned the corresponding modifiers. If the hospital identifies a research study service as non-covered on a claim because the hospital believes the service is for research purposes-only, but CMS sees an associated physician professional fee charge for the service, this could cause an inquiry into the physician's billing.

- ABC University receives a grant for a research study that will be conducted at five different hospitals around the country. Since the protocol is the same for each study site, the government would expect to see similar billing practices among the multiple sites. If the study is registered with clinicaltrials.gov, CMS will know the identity of all the sites. If any of the sites have non-compliant research billing practices, the entire study could end up audited or investigated.

New Terminology from CMS

The CMS transmittals that mandate the new modifier rules use at least three new terms for research billing: "approved clinical research study," "investigational clinical service," and "routine clinical service." These terms are different from the terminology used in the Medicare Clinical Trial Policy (CTP) (National Coverage Determination 310.1), which uses "qualifying clinical trial" and "routine cost." The CMS transmittals use terminology similar to what CMS proposed in its 2007 attempt to revise the CTP. The proposed changes to the CTP in 2007 were not adopted by CMS.

The new terms apply to all clinical research studies and not just those that fall under the jurisdiction of the CTP. The new terms allow Medicare to have a common lexicon for all research studies.

The formal change to the Medicare Claims Processing Manual does not define the term "approved clinical research study," but the CMS transmittals liberally use the concept of an "approved clinical research study" to designate any clinical research study that qualifies for services to be covered. While CMS did not discuss why it decided to use these new terms, the agency has presumably adopted these terms in order to begin harmonizing the device trial coverage rules and the non-device trial coverage rules.

These different coverage rules depend on the type of research study and cause numerous operational challenges for providers as well as confusion over which rule to use and when. Using common terminology for

all research studies, as the modifications do, is a step in the right direction.

Currently, the choice of rules for coverage of research services depends on the type of research study. There have loosely been three types of research studies from the perspective of Medicare: studies that fit under the device trial rules; studies that fit under the CTP; and, other research that is not contemplated by either of these two sets of rules.

The basic coverage rules for device trials are contained in regulations and are discussed in detail in Chapter 14 of the Medicare Benefit Policy Manual. A device trial with an Investigational Device Exemption (IDE) qualifies for coverage only after Medicare contractor approval, and coverage differs depending upon whether the IDE has been classified by the FDA as either a Category A device or a Category B device.

Meanwhile, the CTP sets out the coverage rules for non-device studies and requires a study to meet the "qualifying clinical trial" criteria in order for services to be reimbursable from Medicare.

A variety of studies do not fall under the device trial regulations and are not described by the CTP; examples of such studies include on-label device studies, studies of investigational procedures that do not involve a study drug or study device, and so-called "head to head" studies of multiple conventional care arms. In October 2007, CMS advised providers to bring these studies that fall through the gap to the local Medicare contractor for approval.

Although the concept of an "approved clinical research study" is not clearly defined in the CMS transmittals, the move to use a common term for studies that qualify for Medicare coverage under different sets of rules will help simplify research billing terminology.

Identifying Investigational & Routine Clinical Services

The new modifier rules require a binary choice for all study-related services. A service is either an "investigational clinical service" or a "routine clinical service."

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An investigational clinical service is essentially the thing (drug, device, procedure) that is being studied in the research. A routine clinical service is similar to the term "routine cost" in the CTP and includes items and services that are conventional care or provided for the clinical management of the patient.

- Investigational clinical services are defined as: "those items and services that are being investigated as an objective within the study. Investigational clinical services may include items or services that are approved, unapproved, or otherwise covered (or not covered) under Medicare."

- Routine clinical services are defined as: "those items and services that are covered for Medicare beneficiaries outside of the clinical research study; are used for the direct patient management within the study; and, do not meet the definition of investigational clinical services. Routine clinical services may include items or services required solely for the provision of the investigational clinical services (e.g., administration of a chemotherapeutic agent); clinically appropriate monitoring, whether or not required by the investigational clinical service (e.g., blood tests to measure tumor markers); and items or services required for the prevention, diagnosis, or treatment of research related adverse events (e.g., blood levels of various parameters to measure kidney function)."

V70.7 Code

The January 2008 CMS transmittals left in place the rules on the V70.7 diagnosis code. This code must be placed on the claim form for all approved clinical research studies. The code is placed as the secondary diagnosis on the CMS 1450 form and the CMS 1500 form if the patient is enrolled in the research study for therapeutic purposes.

Services Paid for by the Sponsor

Some confusion in the industry has developed over whether the new modifier rules require that services that are paid for by the sponsor or otherwise provided

free to the patient must be included on the claim form and identified with the Q0 modifier. The confusion is likely due to the definition of "investigational clinical services" which references using the Q0 for services that are "not covered." There does not appear to be any mandate in the modifier rules, or the definition of investigational clinical services, that all non-covered services be listed on the claim and coded with the Q0 modifier.

Nevertheless, the CMS transmittals restated (and presumably must be considered to be reemphasizing) the Medicare Claims Processing Manual mandate that the provider disclose a free Category B IDE device on the claim form. Chapter 32, Section 68.4 states: "Institutional providers must bill the Category B IDE Number on a 0624 revenue code line with charges in the covered charge field (providers receiving the device free of charge must bill the IDE charges as non-covered)."

What Should Providers Do?

While the new modifier rules may not appear earth-shattering on the surface, the CMS transmittals actually represent a bold new move to gather data and monitor clinical research billing activities. The aggregation of the data adds particular risk to multi-site research study billing. Providers should consider the following actions:

1. Develop a process to perform coverage analyses of each research study that sorts the protocol required services into either "investigational clinical services" or "routine clinical services."

2. Institute a process to appropriately place modifiers on claims.

3. Consult the local Medicare contractor to determine the medical director's position on studies that do not fit within the device trial rules or the CTP and what criteria the contractor will use to consider a study an "approved clinical research study."

4. Identify the studies the provider is undertaking that are multi-site and confer with the lead site to determine if any effort has been organized to identify which services should be coded as Q0 or Q1 during the study.

5. Begin a clinical research billing compliance initiative to build safeguards for accurate billing – in advance of audits or reviews by the government or the Medicare contractors.

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