# Client Advisory: Clinical Trials NCD Draft Revisions

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## CMS Issues Draft Clinical Research Policy

The Medicare Program has issued proposed revisions to its rules on coverage of clinical trial services. The draft changes were posted on the CMS website on April 10, 2007 and could be welcome clarifications to one of the most complicated Medicare billing rules.

The changes may also pose new reimbursement challenges for health care providers conducting medical research. The draft changes propose substantial revisions to what is currently called a "qualifying clinical trial."

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The current rule is set out in the Clinical Trials National Coverage Determination but will now be referred to as the Medicare Clinical Research Policy ("CRP"), according to the CMS decision memorandum. CMS believes the term "clinical trial" is not broad enough and proposes to address "research studies" generally.

Under a statutory timetable, CMS must finalize its revisions by July 9, 2007. There is a 30 day public comment period underway. The materials released by CMS total 41 pages.

Overall, the basic concept contained in the current Clinical Trials NCD remains intact in the draft CRP. A research study will first need to qualify for coverage and then every item and service required by the study will need to be analyzed to determine whether it is a routine clinical service and meets all other Medicare rules.

CMS clarifies that any item or service that is covered outside of a clinical trial will be covered during a clinical trial, even if it is the investigational item or service. The draft revisions change the term "routine cost" to "routine clinical services" to better capture the policy that what Medicare is paying for are services that are for the clinical management of the patient.

## Qualifying Clinical Trial Changes

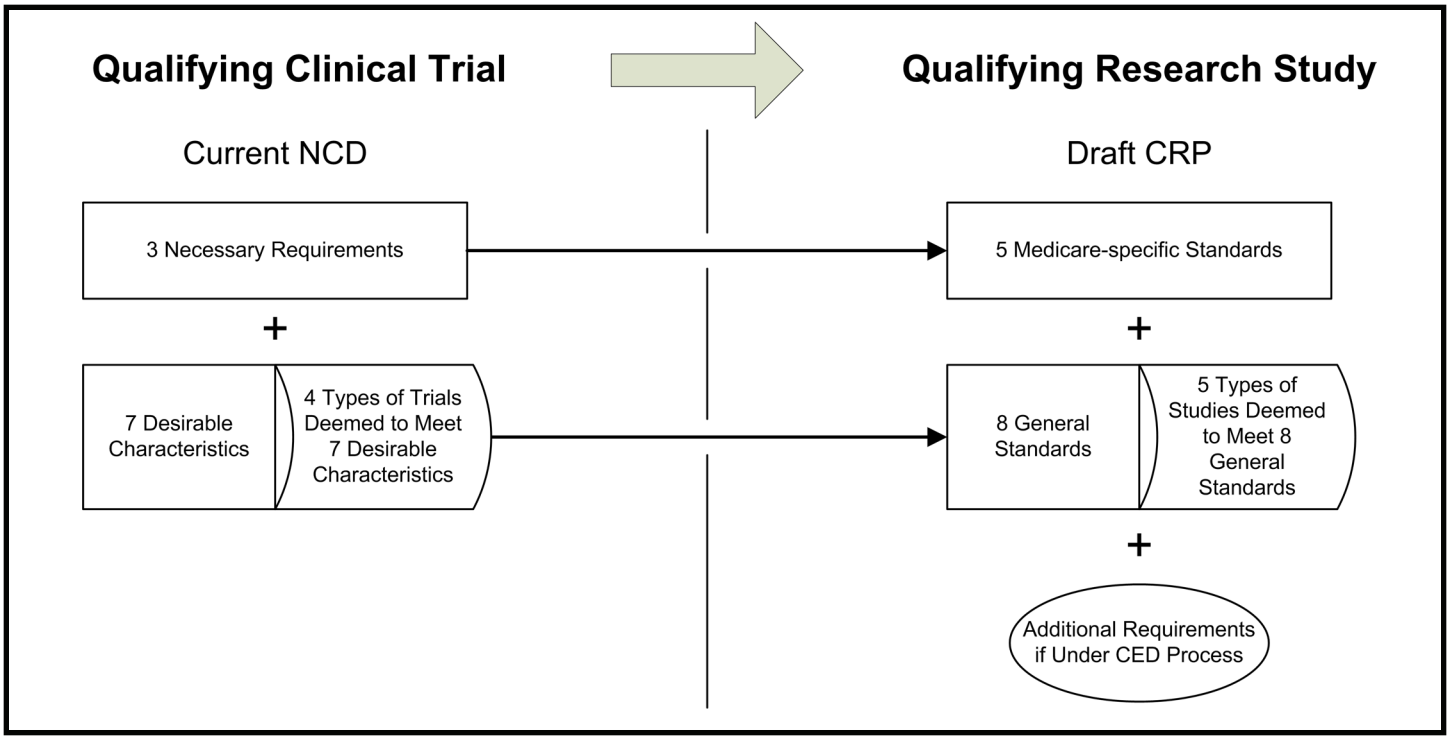
The most significant changes come in what is considered a qualifying research study under the draft CRP. Currently, to be a qualifying clinical trial the Clinical Trials NCD requires a study to meet three necessary requirements and seven desirable characteristics – with only four ways for a trial to meet all seven desirable characteristics (the so-called "deemed trials"). The draft CRP keeps the two-part test but revises the three necessary requirements into five requirements to be called "Medicare-specific standards." The draft CRP also changes the seven desirable characteristics to "general standards" and adds an eighth. The new rules would keep the "deeming" process in place and deem five types of research studies to meet the general standards. For a visual illustration, see diagram on page 2.

The draft CRP also allows CMS to add additional requirements for a qualifying study if the research is being conducted as part of a specific NCD that is utilizing Medicare's coverage with evidence development ("CED") process.

## Medicare-specific Standards

CMS has proposed five Medicare-specific standards that a research study must first meet. These would replace the initial three necessary requirements in the current Clinical Trials NCD. Under the proposed CRP, the study will have to satisfy all of the following to be a qualifying research study:

1. The clinical research study is not designed to exclusively test toxicity or disease pathophysiology. Research studies, including some Phase I trials, whose protocols commit to measuring therapeutic outcomes as one of the objectives, may meet this standard only if the disease being studied is chronic,




life threatening, or debilitating.

2. The research study is registered on the ClinicalTrials.gov website prior to the enrollment of the first study subject.

3. The research study protocol specifies and fulfills method and timing of public release of all pre-specified outcomes to be measured including release of outcomes if outcomes are negative or study is terminated early.

4. The research study protocol must have explicitly discussed inclusion criteria and considered relevant subpopulations (as defined by age, gender, race/ethnicity, socioeconomic or other factors).

5. The research study protocol contains a discussion of how the results will generalize to the Medicare population to infer whether Medicare patients may benefit from the intervention. In particular, the protocol describes the potential impact of age-specific and other factors on outcomes and whether the research study is powered sufficiently to draw conclusions with respect to the Medicare population.

Only the first standard tracks with one of the previous necessary requirements. The second through fifth standards are new and already highly controversial. Significantly, standards three through five affect the research study design and require certain discussions or activities to be hard-wired into the research study's scientific protocol. This is evidence that CMS is looking very carefully for specific technical matters in the protocol itself and would not accept the standards being evidenced generally in the research study.

The first Medicare-specific standard answers a long-debated question over when a research study has sufficient therapeutic intent for Medicare to allow coverage. CMS is backing away from previous interpretations that therapeutic benefit must be evidenced in the primary objectives of the protocol. The revision allows a study to meet the therapeutic intent criterion if therapeutic benefit is one of the secondary objectives as long as the study is investigating therapies in a disease that is "chronic, life threatening, or debilitating."

The clarification of therapeutic intent will significantly help early-stage cancer research that is conducted in Phase I drug trials. However, many non-cancer Phase I studies will still not meet this criterion.

## General Standards

The "highly desirable characteristics" are now called "general standards" under the draft CRP and an eighth standard is added – that the research study have a written protocol.

In the current NCD there are two options for meeting the desirable characteristics: self-certification and the "deeming" process. The draft CRP eliminates the self-certification option, which was never operationalized by CMS. The draft CRP leaves in place the deeming process – that only certain types of research studies are "deemed" to meet the general standards.

Under the draft CRP there are five types of studies that are deemed to meet the general standards:

1. Studies of health outcomes reviewed and funded by a program component of DHHS, the Veterans Administration, or the Department of Defense;

2. Studies reviewed and approved by health care research centers or cooperative health care research groups, funded by one of the above Federal Agencies, provided that the Federal Agency reviews and approves the applicant research centers' or cooperative research groups' subcontract and sub-grant funding requirements, selection procedures and oversight methods, and determines that those processes provide the same level of protocol review as provide by the supporting Federal Agency;

3. Studies conducted under an Investigational New Drug (IND) when the FDA has reviewed the study protocol and the IND has not been put on hold;

4. The study is required and approved by FDA as a post-approval study; or

5. The study is required as an outcome of the NCD process using CED.

The first change to the deemed trial list is the expansion of coverage for research studies funded by any Department of Health & Human Services agency rather than just the handful listed in the current Clinical Trials NCD. CMS is not, however, proposing to expand coverage to any research study funded by any Federal agency.

The most significant change to the list of deemed trials is the elimination of IND-exempt drug studies. In order for an IND-exempt study to qualify for coverage, it must be one of the other types of deemed trials. This change could have a significant effect on investigator-initiated studies.

Without Medicare coverage for IND-exempt studies, investigators and other health care providers will need to make tough choices whether to offer research patients free care or charge the patient for the clinical trial services.

## Clarification of Routine Clinical Services

In a significant improvement to the clarity of Medicare policy, CMS clarifies what it considers to be "routine clinical services" which are covered during a qualifying research study. CMS supports its previous interpretation that anything covered outside the research study will be covered during a qualifying research study.
Specifically, the draft CRP sets out the following examples of routine clinical services:

- items and services that are available to Medicare beneficiaries outside of a clinical study, other than items or services that meet the definition of investigational clinical services;
- only those items and services used for patient management within the study;
- items or services required solely for the provision of the investigational item or service (e.g., administration of a non-covered chemotherapeutic agent);
- the clinically appropriate monitoring of the effects of the item or service (e.g., blood tests to measure tumor markers); and
- items or services required for the prevention, diagnosis, or treatment of complications (e.g., blood levels of various parameters to measure kidney function).

"A research study will only be considered qualifying if it has all five Medicare-specific standards and is one of the five types of studies deemed to meet all eight general standards."

## Summing Up the Draft CRP

The current Clinical Trials NCD is often summed up as allowing coverage for "routine costs" during qualifying clinical trials. Structurally, the draft CRP does not change these concepts because the draft CRP would allow coverage for "routine clinical services" only during qualifying research studies. However, a research study will only be considered qualifying if it has all five Medicare-specific standards and is one of the five types of studies deemed to meet all eight general standards.

## Other Highlights

Some of the other highlights of the draft CRP include:

- CMS emphasized that no item or service should be billed if it is being "provided free to the Medicare beneficiary or when the study sponsor agreement with investigator sites or the informed consent

documents provided to the patient specify that the clinical service will be provided free to all enrollees."

- CMS confirmed that its policy only applies to Part A and Part B and does not address coverage of prescription drugs under Part D.
- CMS clarified that its policy does not apply to trials studying devices with investigational device exemptions, which are addressed by specific regulations.
- CMS reinforced that Local Coverage Determinations are not withdrawn by the CRP.

## What Does this Mean for Providers?

From a compliance perspective, the draft CRP does not disturb the processes that the health care industry has been implementing over the past year since the landmark Rush University Medical Center self-disclosure and settlement.

Industry practices are increasingly moving toward the development of Medicare coverage analyses ("MCAs") for research studies in order to budget for clinical trials and negotiate a sponsorship agreement. The MCA also provides a tool for accurate billing once patients are enrolled in the clinical trial.

The rules of the Clinical Trials NCD and what may be finalized in the new CRP are just one piece of the compliance puzzle that goes into an MCA and clinical trials billing compliance. Providers must harmonize the Medicare rules with the compensation arrangement of the sponsorship contract as well as ensure that whatever services are promised free in the informed consent are not billed.

The structural processes needed to coordinate information in the study documents will be mostly unphased if CMS adopts the draft CRP. A revised rule may change the outcome of whether some research studies qualify for coverage, but health care providers must still establish structures that ensure that accurate billing is occurring and all of the rules, documents and institutional commitments are harmonized.

## What Providers Must Do Under the Current NCD and Draft CRP

Under both the current Clinical Trials NCD and draft CRP providers must:

- Analyze each clinical trial to determine if it is a qualifying study
- Analyze items and services in qualifying studies to determine if they meet the criteria for a routine cost or routine clinical service
- Determine whether the routine costs or clinical services are generally covered by Medicare outside of a clinical trial
- Establish processes to ensure that whatever items and services are being paid for by the sponsor or promised free in the informed consent are not being billed to Medicare, even if the item or service meets the definition of a routine cost or clinical service

## Moving Toward a Final Policy

The health care industry will be keeping a careful watch on the Medicare Clinical Research Policy with an eye toward July 9, 2007. Coverage for clinical trial services in the United States is moving into a new era and health care providers will need to stay on top of these changes to ensure their compliance processes keep up with the changing rules.

The proposed CRP can be found at the CMS website at www.cms.hhs.gov/apps/media/press/release.asp.

If you have any questions about the proposed CRP, please contact:

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