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FDA Accepting Comments on Proposed Program to Integrate FDA Premarket Approval and CMS Coverage Decision-Making Process

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On September 17, 2010, the Centers for Medicare & Medicaid Services ("CMS") and the U.S. Food and Drug Administration ("FDA") issued a notice in the Federal Register requesting public comment on a proposed new program referred to as "parallel review" ("Comment Request").[1] This program would give drug and device sponsors the option of receiving an FDA premarket evaluation and a Medicare National Coverage Determination at the same time. By reducing the waiting times associated with CMS and FDA product evaluations and decreasing the likelihood that product sponsors will have to conduct separate clinical studies for each agency, CMS and FDA believe that parallel review will hasten consumer access to new innovative products and minimize the burden that FDA reviews and Medicare National Coverage Determinations impose on drug and device sponsors. These changes will not only affect parties who are interested in drug and device innovation, but providers, payers, and health care consumers as well.

CMS and FDA are requesting comments from the public on all aspects of the proposed parallel review process by December 16, 2010. For individuals with an interest in shaping the parallel review process, now is the time to comment.

FDA and CMS already began the process of developing a framework for parallel review. By a Memorandum of Understanding entered into on June 25, 2010, the agencies have agreed to collaborate, exchange information, and build an infrastructure for parallel review.[2] After reviewing the public comments on parallel review, CMS and FDA will begin considering requests from a small number of product sponsors with innovative products for parallel review on a pilot basis. The agencies also intend to use the public comments as a basis for

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[1] 75 Fed. Reg. 57,045 (Sept. 17, 2010).
[2] Memorandum of Understanding Between United States Food and Drug Administration and Centers for Medicare & Medicaid Services, June 25, 2010 (MOU-225-0010). Available at: http://www.fda.gov/AboutFDA/PartnershipsCollaborations/MemorandaofUnderstandingMOUs/DomesticMOUs/ucm217585.htm.

developing a draft joint guidance that will describe the parallel review process. A second round of public comments will commence, following publication of a draft joint guidance.[3]

History and Program Objectives

Presently a product sponsor must obtain FDA clearance or marketing approval before it can request a National Coverage Determination from CMS. The FDA premarket evaluation and the National Coverage Determination can each require many months, in some cases years, of agency review. Sponsors must prepare separate submissions of clinical trial materials to both the FDA and CMS even though there is some overlap in the information required by the two agencies. The disconnect between these two evaluation processes, as noted by CMS and FDA in the Comment Request, delays consumer access to innovative products, produces unnecessary costs due to the duplication of efforts, and sometimes results in the development of clinical trial designs during the FDA phase that fail to address questions relevant during the CMS National Coverage Determination process.[4]

According to FDA and CMS, the parallel review program will seek to address the inefficiencies associated with entirely separate review pathways for FDA approval and CMS coverage without altering the distinct regulatory and statutory standards the agencies use for decision-making.[5] Most notably, the FDA focuses its processes on determining "safety and effectiveness," while CMS focuses on "items and services that are reasonable and necessary for the diagnosis or treatment of an illness or injury" and are within the scope of a Medicare benefit category. Ultimately, CMS decides which items and services it can and should pay for, how it should accomplish the payment, and how much it should pay under the Medicare program.[6]

Questions Posed by FDA and CMS

As previously noted, FDA and CMS have requested comments on all aspects of the parallel review program. Specific areas of inquiry are listed in the Comment Request. A subset of those topics is provided below:

- What types of products should be eligible for the parallel review process? The agencies describe parallel review as a program for "innovative" products. How should this term be defined?

- Should a voluntary process be developed under parallel review that will help sponsors develop clinical trial designs that are consistent with the evaluation criteria for both FDA approval and CMS coverage determination?

- At what point during the FDA process should parallel review begin? How should the agencies balance the efficiency objectives of parallel review with the risk that CMS will initiate a National Coverage Determination on a product that fails to receive approval by the FDA?

[3] 75 Fed. Reg. 57,047 (Sept. 17, 2010).
[4] *Id*. at 57,047.
[5] *Id*. at 57047.
[6] 75 Fed. Reg. 57,045, 57,046 (Sept. 17, 2010).

- Should the parallel review process include joint agency meetings with interested sponsors? If yes, at what point during the process should these meetings occur?

- Should FDA and CMS have access to the same product information during the parallel review process?

- How should the agencies reconcile the confidential nature of the FDA approval process with CMS's policy of publicly announcing the beginning of National Coverage Determinations?

- What steps should the agencies take to minimize duplication of data submissions?

- Should the agencies permit a product sponsor to withdraw its request for parallel review once initiated?

- Should the current medical device user fee that product sponsors pay to FDA be altered to support additional FDA costs associated with parallel review?

Comments

We encourage all interested stakeholders to submit comments to this Comment Request regardless of whether one knows today whether he or she would use this process. That way, an attractive process could be available should it be desired at a later time. Not all medical device companies may want such a parallel process for each product. For example, the product may receive little use by Medicare beneficiaries such that a CMS National Coverage Determination is not desired. Even when a product will be used by the Medicare population, it could be very risky to pursue a CMS National Coverage Determination at the outset of the FDA process. Instead, many device companies use Medicare claims administrators to consider new products for coverage. This is because an unfavorable National Coverage Determination from CMS cannot be remedied or offset by favorable coverage determinations by Medicare claims administrators.

Developing clinical trials targeted at the FDA approval process also may be an easier undertaking. For example, most often, FDA approval trials are placebo-focused trials. However, CMS may have a greater interest in comparative clinical effectiveness trials, *i.e.,* trials that compare the new product to other products in the marketplace. There also are the general risks associated with any new government program that has not yet developed a track record of success. Ultimately, it would be helpful for interested parties to comment now so that parallel review could be a viable option for those situations where it could be appropriate and attractive in the future.

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This Client Alert was authored by ***Lynn Shapiro Snyder***, ***Jason B. Caron***, *and* ***Ross K. Friedberg****. For additional information about the issues discussed in this Client Alert, please contact one of the authors or contributors or the EpsteinBeckerGreen attorney who regularly handles your legal matters.*

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