FDA AND CMS ANNOUNCE INTENTION TO COLLABORATE IN TWO MAJOR AREAS

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All companies within the health care industry should be aware of two recent developments in the area of medical device approval and federal health care program reimbursement.

Recently two Federal Register notices were published heralding the beginning of collaboration between the Food and Drug Administration (FDA) and the Centers for Medicare and Medicaid Services (CMS) in reviewing new medical products. Given the very different legal standards for FDA product approval and CMS coverage and payment for new devices, the entire health care industry should be following these collaborative efforts carefully.

Memorandum of Understanding

On August 11, 2010, the FDA published notice of a Memorandum of Understanding (MOU) between the FDA and CMS related to the exchange of information between the two agencies. Specifically, the agencies (referred to as federal partners) stated that the purpose of the MOU "is to promote collaboration and enhance knowledge of efficiency by providing for the sharing of information and expertise between the federal partners." The agencies outline goals, including:

- Exploring "ways to further enhance information-sharing efforts through more efficient and robust inter-agencyactivities;
- Promot[ing] efficient utilization of tools and expertise for product analysis, validation, and risk identification;
- Build[ing] infrastructure and processes that meet the common needs for evaluating the safety, efficacy, utilization, coverage, payment, and clinical benefit of drugs, biologics, and medical devices."

The purpose of this broad MOU appears to be to lay the foundation for efficient and secure exchange of information between the FDA and CMS in anticipation of the agencies potentially working together to review new products. The agreement outlines the steps the agencies will take to create a mechanism for exchanging information. This will include meeting to determine the policies and procedures that must be drafted to implement the MOU, appointing individuals to be each agency's "point of contact" to facilitate communication between the agencies, and ultimately

drafting policies and procedures regarding the type of information that may be exchanged and the circumstances under which the information can be properly exchanged. The MOU became effective once signed by both the FDA and CMS (the later signing date by the FDA was June 25, 2010) and remains in effect for five years unless otherwise terminated. The agreement may be terminated by either party with 60 days written notice.

At this point, the MOU itself fails to address how any information exchanged will actually be used by each of the federal partners.

Parallel Review of Medical Products

Along those lines, on September 17, 2010, the FDA and CMS published notice of their intention to simultaneously review pre-market applications for FDA-regulated medical products. The primary factor that appears to be motivating this potential collaborative effort is the desire to streamline the process whereby new, innovative products reach the market quickly and in a cost-effective manner. Indeed, the "agencies believe they should address the growing need to improve public health by speeding consumer access to and spurring the development of new, affordable, reliable, safer, and more effective medical products and services." They note that parallel review provides them with the opportunity to work together to achieve these goals.

However, parallel review is not without obstacles.

The agencies discuss the current process of evaluation and note that new medical products are reviewed serially, with FDA first evaluating the safety and effectiveness of medical products and CMS subsequently evaluating whether a product is "reasonable and necessary to diagnose or treat an illness or injury affecting the Medicare population."

The agencies note that such serial review has traditionally occurred for a number of reasons. First, CMS typically would not provide coverage to a product that has not been cleared or approved by the FDA to be marketed in the United States. By waiting until after a medical product has been cleared by the FDA, it is ensured that it will not waste its limited resources on the evaluation of products that are never ultimately approved by the FDA. Second, CMS has strict statutory time limits from the time it begins a national coverage determination (NCD) evaluation until its final determination is published, which cannot be extended if the FDA has not yet approved the product. Third, CMS has a policy of informing the public "when it begins an NCD process for a particular product." On the other hand, FDA regulations specify that pre-market applications typically remain confidential to ensure that commercial information is not revealed while a product is under evaluation.

These are clearly potential roadblocks that the agencies will need to address, particularly the differing review standards. The nature of the evaluations performed by these agencies necessitates that different questions be examined. The FDA, charged with evaluating safety and effectiveness, undertakes different reviews depending on the nature of the pre-market submission. For example, in the case of a 510(k) review, the FDA will assess whether a medical device is "substantially equivalent" to a currently marketed device. When a medical device is reviewed under the pre-market application (PMA) standard, however, a product sponsor must independently establish its safety and effectiveness. CMS, concerned with determining whether to pay for certain products and services, will often consider outcomes data, "whether the product provides improved, equivalent, or complementary health outcomes … compared to alternative treatments or diagnostics …" and may also

"evaluate medical product indications that have not been approved or cleared by FDA" (i.e., off-label uses).

The FDA and CMS have proposed the possibility of meeting with sponsors during the parallel review process. The agencies propose a "voluntary process to allow companies to meet with both agencies to develop clinical trial protocols that would meet each agency's respective statutory standard rather than potentially conducting separate clinical studies."

The agencies make clear that the "regulatory standards and evidentiary standards used by the FDA and CMS for decision-making would not change." Again, the health care industry should carefully monitor the collaboration as it has the potential to significantly impact the FDA review process and product reimbursement.

Public comments are requested by the agencies on numerous topics, including:

- The disadvantages of and barriers to parallel review
- The conflicting mandates to keep certain commercial information confidential during the FDA review process and to make public the commencement of an NCD determination
- Increased research and development costs to product sponsors and prolongation of the process of both FDA approval or clearance and NCD determinations