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Client Alert

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A Recent Memorandum of Understanding Between FDA and CMS To Facilitate Information Sharing May Accelerate Approval and Coverage Decisions for FDA-Regulated Products

Recently, FDA Commissioner Margaret Hamburg signed a Memorandum of Understanding (MOU) with the Centers for Medicare & Medicaid Services (CMS) to "promote initiatives related to the review and use of FDA-regulated drugs, biologics, medical devices, and foods, including dietary substances." MOU 225-10-0010 (June 25, 2010) can be found here.

The MOU, which went into effect in July, should authorize expanded information sharing between the two agencies, and is designed to achieve two principal goals:

- Promote efficient utilization of tools and expertise for product analysis, validation and risk identification, and
- Build infrastructure and processes that meet the two agencies common needs for evaluating the safety, efficacy, utilization, coverage payment, and clinical benefit of drugs, biologics, and medical devices.

The way in which this CMS-FDA collaborative process will work is not described in the MOU, and instead is to be determined in meetings between the agencies, the first of which is to take place within 30 days of the release of the MOU. The MOU merely states that the specific procedures and safeguards necessary to implement the MOU will be determined by mutual agreement of the two agencies. The MOU does, however, make clear that the collaborative process will be built around a structure that will safeguard confidential information. Specifically, the MOU provides that administrative, technical, procedural, and physical safeguards against unauthorized disclosure of protected health information, trade secrets, and other confidential commercial information will be implemented. Additionally, the agencies agree to protect against unauthorized use of shared information by implementing procedures to ensure that shared information is only used in compliance with the Trade Secrets Act, the Privacy Act, the Federal Food, Drug, and Cosmetic Act, the Freedom of Information Act, and the Health Insurance Portability and Accountability Act (HIPAA) .

In recent years, the FDA and CMS have on occasion expressed a desire to share information in order to facilitate parallel reviews between the two agencies when an applicant is seeking FDA marketing approval and CMS coverage decisions concerning a medical product. However, little joint action has occurred to compress the timeline to approval and coverage

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determinations other than the 2003 coverage and reimbursement for Johnson & Johnson's drug-eluting stent, which became effective upon FDA approval. This MOU, if fully implemented, may be a step in that direction and allow for Medicare coverage and payment determinations to more commonly become effective upon FDA approval.

The principal points of interest in the MOU include:

- The designation of a single point person for FDA and CMS for all requests for inter-agency informan sharing.
- The intent that requests for information sharing will be honored unless the recipient agency has good reason otherwise, such as lack of staff to fulfill the request, where the request is too burdensome, or there are legal prohibitions to responding.
- An agreement to establish procedures to guard against inappropriate or unauthorized disclosure of trade secrets, protected health information, or proprietary commercial information.
- An acknowledgement that the MOU does not change any legal or regulatory powers or responsibilities of either agency.

The potential benefit of the MOU is that the expertise and knowledge of the staff in one agency will become available to the other, and of course, such collaboration could result in better and more informed decision-making. The challenge will be in developing a process of sharing data that will, indeed, streamline and push forward each agency's decisions. Both agencies have different principal missions. FDA's purpose is to determine whether medical therapies and technologies are safe and effective for their intended uses. CMS' focus, on the other hand, is on coverage and payment and the reckoning that a particular medical therapy or technology is reasonable and necessary to diagnose or treat the Medicare population. Consequently, it remains to be seen whether, for example, FDA's decisions on safety and efficacy for a particular drug will influence CMS determinations for coverage when that drug is prescribed for an off-label use. Similarly, one can question whether CMS' concentration on patient outcomes and comparative effectiveness will affect FDA's review of safety and effectiveness?

Thus, the MOU's stated goal of building an infrastructure that meets the common needs for both product approval and coverage determinations will be complicated by the fact that the two agencies need to evaluate somewhat different factors to meet their primary missions. In the final analysis, the utility of this MOU to foster meaningful parallel review will likely depend on whether, in a majority of instances, there will be sufficient relevant information to share and whether this information sharing will truly accelerate the decision-making process at each agency.

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