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Life Sciences Health Industry Alert

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CMS and FDA Publish Parallel Review Pilot Program Notice

Overview

On Friday, October 7, 2011, the Centers for Medicare & Medicaid Services ("CMS") and the Food and Drug Administration ("FDA") (collectively, the "Agencies") announced they were soliciting nominations from sponsors of medical devices to participate in the Agencies' parallel review pilot program. The Agencies officially published a *Federal Register* notice announcing the program October 11, 2011 (the "Notice"), with an effective date of November 10, 2011, although the Agencies began accepting nomination submissions October 7.[1]

The Agencies are soliciting nominations from "sponsors" – presumably, manufacturers – of "innovative medical device technologies." Notably, drugs and biological manufacturers are not included in this pilot program, although the Agencies state that they intend to use their experience with the medical device pilot program to expand the program to include drugs and biological products in the future. The Notice outlines the procedures for participation in the pilot program, emphasizes the voluntary nature of the pilot program, discusses the appropriate candidates for the pilot program, and conveys the "guiding principles" the Agencies plan to follow in implementing the pilot program. The Agencies intend to run the pilot program for two years, with the possibility of an extension beyond the two-year program or termination prior to the end of the two-year program. Because of constrained resources, the Agencies plan to accept only three to five nominations for parallel review per year.

The following *Alert* summarizes the Notice and discusses potential implications for manufacturers that may be considering participation in the pilot program.

Background

The Notice follows the Agencies' notice with request for comments published September 17, 2010, which proposed the creation of a voluntary parallel review program. The Agencies' proposed parallel review pilot prompted a variety of organizations and individuals to submit comments, including medical device and drug manufacturers, patient advocacy groups, medical societies, and providers. Reed Smith discussed the comments received by the Agencies in its Life Sciences Health Industry *Alert* titled, "Prospects Unclear for CMS/FDA Proposed Parallel Review of Medical Products."

As discussed in our previous *Alert*, the commenters generally expressed significant reservations about the Agencies' proposed parallel review pilot program. Specifically, many comments highlighted concerns that the National Coverage Decision ("NCD") process was not the best option for most new medical products when seeking a Medicare coverage decision, and urged that the parallel review process be voluntary, and protect trade secrets, proprietary information, and confidential commercial information.

The current Notice relates some of the concerns articulated in the comments the Agencies received, and also notes that the Agencies plan to seek feedback and input from pilot program participants as the pilot program goes forward.

Purported Benefits of Parallel Review Program

The Agencies identify what they perceive to be the multiple benefits of the parallel review program in the Notice, including the following:

- The public interest could be served by reducing the time between FDA marketing approval or clearance decisions and Medicare NCDs.
- Patients could gain quicker access to innovative medical technologies if covered.

- Sponsors/requester would gain timely insight to CMS's information needs associated with a positive NCD, as well as a potentially shortened time to payment resulting from the streamlined multi-review process.
- CMS's early involvement will streamline its decision-making process, focus attention on health outcomes of importance to Medicare, and alert requestors to any remaining evidence gaps. Such gaps could be addressed by implementing coverage with evidence development ("CED") or other policy vehicles. For instance, if FDA approval or clearance is conditioned on a post-approval study, CMS might cover the device within the parameters of the post-approval study under CED.[2]

Guiding Principles of Parallel Review Pilot Program

In an apparent effort to address concerns raised by commenters, the Notice lists the "guiding principles" of the parallel review pilot program. For example, the Agencies state they will not publicly disclose a medical device's participation in the pilot program until CMS's posting of the NCD tracking sheet, unless the sponsor/requester consents, public disclosure is required by law, or the sponsor/requester has already made the information public. Until CMS posts the NCD tracking sheet, the sponsor/requester can withdraw from the pilot program, or the Agencies can terminate their parallel review. The guiding principles also indicate the Agencies will follow the requirements contained in the Agencies' memorandum of understanding. In recognition of a lack of resources, the Agencies state that they plan to limit parallel review to only three to five submissions per year.[3]

Appropriate Candidates for Parallel Review Pilot Program

The Notice indicates that appropriate candidates for parallel review are devices that already have entered preliminary FDA review stages, such as:

- New technologies for which the sponsor/requester has had sufficient pre-investigational device exemption ("IDE") interaction with FDA or approved IDE application.
- New technologies for which an original or supplemental application for premarket approval ("PMA") or a petition for de novo review would be required.
- New technologies that fall within the scope of Part A (coverage of inpatient care in hospitals, skilled nursing facility, hospice, and home health) or Part B (medically necessary doctors' services, outpatient care, home health and other medical services) Medicare benefit categories that are not subject to an existing NCD.[4]

In any case, the appropriate candidate will likely need to provide sufficient data to support safety and efficacy necessary for FDA approval *and* demonstrate a medical benefit to Medicare beneficiaries. Although the Notice and previous communications on parallel review have been silent on such details, the Notice encourages potential participants with questions about the program to contact the FDA via email prior to initiating participation.[5]

Procedures for Pilot Program

It is important to note that it is the sponsor/requester of an innovative therapeutic or diagnostic device that nominates its device for participation in the pilot program—making the pilot program voluntary. Assuming a potential participant has contacted the FDA and received sufficient information to decide to go forward, the sponsor/requester must then follow the procedures outlined in the Notice in order to participate in the pilot program.

Broadly described, the sponsor/requester nominates its device for participation in the pilot program by following instructions at *http://www.parallel-review.fda.gov.*[6] According to the Notice, this nomination process will be a "secure and confidential" process managed by the FDA. The Agencies will then meet within 30 days after the submission of a nomination to determine if the device would be appropriate for parallel review, and will notify the sponsor/ requester accordingly. The FDA will review the device according to the normal FDA review process. CMS will begin its informal review after the device sponsor/requester submits the de novo petition or the PMA.

As mentioned above, if a sponsor/requester wishes to withdraw from the parallel review pilot program, it must notify the Agencies in writing before CMS posts the NCD tracking sheet.

Discussion

Commenters responding to the September 2010 notice expressed considerable reluctance to participate in any pilot parallel review process that included an automatic pathway to an NCD. This is because an NCD is binding on all Medicare carriers, fiscal intermediaries, Quality Improvement Organizations, Health Maintenance Organizations, Competitive Medical Plans, Health Care Prepayment Plans, the Medicare Appeals Council, and Administrative Law Judges. As a consequence, the possibility of a negative NCD poses a great risk for medical device manufacturers because it could severely limit the device's coverage, including precluding local coverage. Given this risk, the pilot program's reliance on the NCD process will very likely reduce the number of interested sponsors/requestors.

As previously discussed, the Notice cites multiple purported benefits of proposed parallel review, including that the process "will serve the public interest by providing the possibility of reducing the time between FDA marketing approval or clearance decisions and Medicare NCDs." However, until the pilot program is actually implemented, it remains unclear whether or not it will actually increase efficiency and expedite the review process.

Moreover, the Agencies do not address questions that the proposed Notice inevitably raises, such as:

- How will sponsors of innovative technologies develop data to address the economic and comparative evidence necessary to support a positive NCD during pivotal trials?
- How will the joint Agency review and handle such issues as cost effectiveness and comparative efficacy, and what mechanism exists for resolving internal Agency disagreement related to data collection?
- How will the parallel review process interact with CMS's existing NCD process and timelines, including the need for an external technology assessment or Medicare Evidence Development & Coverage Advisory Committee ("MEDCAC") review?

Always controversial, these questions typically are viewed as being more within the province of CMS than FDA, and how these issues will be resolved in the context of the pilot program remains unclear.

Finally, the NCD provisions and procedures are unchanged by the parallel review process. Thus, although a sponsor may withdraw from the parallel review program, CMS could seemingly still initiate an NCD following FDA approval of the new technology based on information learned during the preliminary "parallel review" discussions.

While informal consultation with the Agencies prior to participation may provide more clarity on outstanding policy issues associated with parallel review, we nevertheless advise sponsors to weigh carefully the potential risks and benefits associated with participation in the pilot program before formally nominating a device.

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1. The Notice refers medical device sponsors interested in the parallel review pilot program to the link http://www.parallel-review.fda.gov for additional information. We note that as of this writing, the link is not active, although related documents have been posted at http:www.fda.gov/MedicalDevices DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions ucm255678.htm.
2. 76 Fed. Reg. 62808 (Oct. 11, 2011).
3. Id. at 62809.
4. Id. at 62809.
5. Id. at 62809.
6. Again, we note that as of this writing, the link, http://www.parallel-review.fda.gov, is not active.

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