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Bioscience Alert

OCTOBER 2011

FDA and CMS Announce Pilot Program for Parallel Review of Medical Devices

On October 7, 2011, the Centers for Medicare and Medicaid Services (CMS) and the Food and Drug Administration (FDA) announced the launch of a pilot program for parallel review of medical devices for FDA approval and Medicare coverage. Under consideration since an initial notice and request for comment released on September 17, 2010, the pilot program will offer certain innovative medical devices an expedited timetable for obtaining Medicare national coverage determinations (NCDs). If you wish to view the initial request for comments, it is available at http://edocket.access.gpo.gov/2010/pdf/2010-23252.pdf.

I. Background.

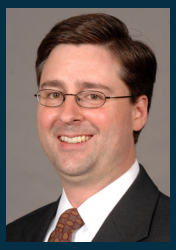
Currently, FDA and CMS consider new medical devices sequentially. First, FDA grants approval or clearance of a medical device after the medical device company demonstrates to the FDA that the product is safe and effective. Upon such approval or clearance, companies may seek coverage under the Medicare program by requesting an NCD. Because CMS may take 9 to 12 months to consider an NCD request, a company often experiences significant delay between FDA approval of its device and the ability to obtain Medicare reimbursement for it. Moreover, CMS's consideration of an NCD request only after FDA approval may delay the public's access to new medical technologies. In light of these concerns, and to create a more efficient and coordinated approval process, the pilot program would have CMS begin its consideration of an NCD request after submission of a premarket approval application (PMA) or *de novo* petition to the FDA.

II. Participation.

Companies interested in participating in the pilot program are encouraged to contact the FDA at parallel-review@fda.gov to discuss the program and the device(s) the company would like to see included in the parallel review process. Given agency resource limitations, FDA and CMS expect to accept no more than 3 to 5 devices per year to participate. When selecting devices, the agencies will "focus on truly innovative technologies that are most likely to benefit from the efficiencies of parallel review." Accordingly, the agencies will look for devices which use new technologies (i) for which the company has had sufficient pre-investigational device exemption (IDE) interaction with the FDA or an approved IDE application, (ii) for which an original or supplemental application for PMA or petition for *de novo* review would be required, and (iii) that fall within the scope of a Medicare Part A or B benefit category and are not subject to an NCD.

After this initial and informal discussion period, a company may nominate its device for participation in the pilot program by following procedures that are to be made available at http://www.parallel-review.fda.gov. (Note: As of publication of this Alert, the website has yet to be activated.)

Questions?
If you have any questions about this alert, please contact:



David M. Mack, *Partner*
dmack@goodwin.com
(860) 251-5058

Nominations should include the following information about the device:

- Name of the sponsor/requester and relevant contact information;
- Pre-IDE/IDE/PMA/de novo reference number;
- Name of the product;
- Succinct description of the technology and disease or condition the device is intended to diagnose or treat;
- Stage of development of the technology; and
- Brief statement explaining why the device is an appropriate candidate for the pilot program.

FDA and CMS intend to meet to consider a nomination within 30 days of receipt and will inform the requesting company of the product's appropriateness for the program upon completion of the agencies' review. The agencies have not elaborated on how they will choose between devices meeting the criteria set forth above or if other criteria will be utilized.

If a device is chosen to participate in the pilot program, FDA and CMS will meet with the company, either in person or by phone, prior to commencing review. The device will be reviewed according to the normal FDA process and participation in the pilot program will not affect fees, timeframes or standards. Upon submission of the PMA or de novo petition, CMS will commence its review.

III. Looking Ahead.

FDA and CMS intend to accept requests to participate in the program for 2 years, presumably from the notice's November 10, 2011 effective date. After the program's end, the agencies intend to use their experience with the pilot program to develop a broader parallel review program for medical devices, drugs and biological products.

If you have any further questions regarding the pilot program or FDA or CMS requirements generally, please feel free to contact David M. Mack at dmack@goodwin.com or (860) 251-5058.

One Constitution Plaza
Hartford, CT 06103-1919
860-251-5000

300 Atlantic Street
Stamford, CT 06901-3522
203-324-8100

1133 Connecticut Avenue NW
Washington, DC 20036-4305
202-469-7750

289 Greenwich Avenue
Greenwich, CT 06830-6595
203-869-5600

12 Porter Street
Lakeville, CT 06039-1809
860-435-2539

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