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FDA and CMS Consider Parallel Review of Medical Products *Seek Public Comment*

On Friday, September 17, 2010, the Food and Drug Administration (FDA) and the Centers for Medicare and Medicaid Services (CMS) jointly announced¹ the consideration of a voluntary process for parallel review of medical products.² The process would allow CMS to begin consideration of a request for a national coverage determination (NCD) before FDA has completed its review of the product's safety and effectiveness. The Agencies expect that this overlapping, parallel review process would decrease the time between FDA approval or clearance and the promulgation of an NCD to ensure CMS coverage and subsequent reimbursement for Medicare beneficiaries (the "approval-to-payment" time). The Agencies intend to test the parallel review process through a pilot program for medical devices.

FDA and CMS are soliciting comment from the public regarding the parallel review process. Comments must be submitted to docket number FDA-2010-N-0308 by December 16, 2010. After reviewing comments, FDA and CMS will issue a joint draft guidance document describing the parallel review process and procedures. At that time, the Agencies will again invite public comment.

Parallel Review Process

Currently, FDA and CMS considerations of a new medical product occur serially; after FDA grants approval or clearance of a product, CMS begins its consideration of an NCD, if requested by CMS or an interested stakeholder. CMS waits for FDA to complete its process first so that CMS does not expend time and resources considering an NCD for a product that ultimately does not receive approval or clearance. Serial processing also ensures that CMS can meet its statutory requirement to complete the NCD within nine to twelve months of beginning the process, because CMS does not have to wait to ensure that the FDA approves or clears the product. This serial review can potentially delay a sponsor's ability to receive Medicare coverage, which can, in turn, delay the public's access to new medical products.

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FDA and CMS believe that in addition to decreasing the approval-to-payment time, parallel review can also provide efficiencies in the creation and submission of clinical studies. Because FDA and CMS often require different clinical data, sponsors at times have to conduct different studies for each agency. CMS and FDA believe that a cooperative and collaborative parallel review will provide the Agencies with an opportunity to inform sponsors much sooner about clinical study designs that could provide data to address both FDA and CMS questions.

Although the Agencies will not provide details of the procedures for the parallel review process until after reviewing the public's comments, the *Federal Register* notice does provide a general outline of the process. First, the process would be entirely voluntary—the manufacturer of a new product would have to request parallel review, including an NCD, and both CMS and FDA would have to agree to the use of the process. Second, CMS's NCD consideration would begin after FDA has begun, but before it has completed, the product's premarket review. The timing of this staggered review process has not yet been determined, but it will be calculated to avoid CMS's issuing of an NCD for a product that is ultimately not approved or cleared, and to avoid conflicting with CMS's nine to twelve month statutory decision deadline. Additionally, the *Federal Register* notice reveals that the Agencies are considering the creation of a process that would allow manufacturers to request a joint meeting with both Agencies to develop clinical trials that would meet the needs of each Agency simultaneously.

The implementation of a parallel review program would not change any of the regulatory or evidentiary decision-making standards for either FDA or CMS. Additionally, the sponsor would still need to meet all current legal and regulatory requirements for FDA approval or clearance and a CMS NCD. However, the Agencies will strive to streamline the processes so that submissions made in the parallel review process are not duplicative and are less burdensome than in the current, serial review paradigm.

Pilot Program for Medical Devices

After reviewing comments submitted regarding the parallel process, CMS and FDA will consider a limited number of requests from manufacturers of "innovative medical devices" for a parallel review pilot program. Procedures for requesting participation and criteria for inclusion in the pilot program will be announced at a later date. Device manufacturers interested in participating in the parallel review pilot program should contact Markham C. Luke in FDA's Center for Devices and Radiological Health (CDRH).³

Requested Comments

FDA and CMS are seeking comments from the public on the parallel review process, both in general and in response to 17 specific topics. Key areas of requested comments include:

- Whether CMS should be permitted to consider off-label uses of a product undergoing parallel review.
- Whether and how a voluntary process should be created that will encourage the conduct of clinical trials that will support both FDA approval or clearance and a CMS NCD decision.



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- How to time the staggered start of FDA and CMS review so that the time between FDA approval or clearance and a CMS NCD decision is decreased, and so that the risk that CMS issues an NCD for a product that is not ultimately approved or cleared by FDA also is avoided.
- Whether FDA and CMS should have access to the same data during parallel review.
- Whether CMS should, with the sponsor's consent, make public that it has begun an NCD review for a product that is still undergoing FDA review and if a sponsor declines disclosure, whether it should be allowed to continue with parallel review and require CMS to not disclose the NCD process (which is contrary to current CMS policy).
- Whether a sponsor should have to consent to informing the public that its product will be considered under parallel review.
- What steps FDA and CMS can take to minimize duplicative data submissions.
- Whether a sponsor should be able to withdraw from parallel review once it has opted in.
- Whether and how the current Medical Device User Fees should be restructured to support additional costs of parallel review.

Implications and Concerns

Disadvantages of Requesting an NCD

Sponsors need to be very cautious in considering whether potential advantages regarding timing of the review processes may be overshadowed by the potential disadvantages of requesting an NCD. Currently, very few therapies and services are reimbursed under an NCD. For the overwhelming majority of novel products approved or cleared by FDA, coverage decisions are made by regional CMS contractors in the absence of an NCD or new products are simply covered and reimbursed under existing codes if there is no question that these existing codes accurately describe the new technology. In the absence of an NCD, although one regional CMS contractor may deny coverage, other contractors may deem that the novel product should be covered. In contrast, a negative NCD means that there will be no coverage and subsequent reimbursement anywhere in the United States. Additionally, an NCD may afford coverage for much narrower indications than those approved by FDA; in this instance, regional CMS contractors have no discretion in considering the indication for which the new product will be covered if the NCD states that no broader coverage may be allowed. Third, an NCD may be accompanied by a requirement for Coverage with Evidence Development (CED). In this instance, the sponsor may be obligated to conduct new clinical studies or develop complex long-standing registries in addition to any FDA-related requirements for postmarket clinical studies.

Off-Label Use



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When CMS considers an NCD for a product, the Agency may evaluate uses that have not been approved or cleared by FDA, that is, off-label uses. FDA, however, only reviews the proposed, labeled indications. Therefore, if a manufacturer wishes to seek an NCD for an off-label use, the parallel review process may create some problems. For example, if CMS shares information with FDA regarding off-label uses under consideration by CMS, FDA may increase its scrutiny of unapproved indications and may require further clinical data or cautionary labeling. Many off-label uses also are covered by Medicare from product launch or shortly thereafter without any formal CMS coverage determination. So this parallel review might actually delay coverage of off-label uses.

Reimbursement Coding

Unless the mechanisms for granting reimbursement codes (HCPCS codes for drugs or devices and CPT codes for new physician services) are also revised, the parallel review system may not actually result in more timely reimbursement for new products. Even if CMS issues a coverage determination sooner after product launch, manufacturers would nevertheless be unable to receive reimbursement if a new code is needed that has not yet been issued. Currently, it takes far too long to obtain reimbursement codes. Applications for new HCPCS codes must be received by CMS the beginning of January of a given year, but new HCPCS codes do not go into effect until the following January 1. The American Medical Association controls the issuance of new CPT codes for new physician services. Obtaining new CPT codes also can easily take from one year to 21 months.

King & Spalding will continue to monitor and provide updates regarding FDA and CMS's proposal for a parallel review process. Please contact us if you have any questions about the parallel review process or if you would like our assistance in the preparation of comments to this Federal Register notice.

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This alert provides a general summary of recent legal developments. It is not intended to be and should not be relied upon as legal advice.

¹ Notice; request for comments, Parallel Review of Medical Products, 75 Fed. Reg. 57045 (Sept. 17, 2010), available at <http://frwebgate3.access.gpo.gov/cgi-bin/PDFgate.cgi?WAISdocID=kfd43e/2/2/0&WAIAction=retrieve>.

² The *Federal Register* notice uses the term “medical products” to describe the products that would be eligible for the proposed parallel review process. CMS and FDA do not define this term, so it is not entirely clear to which products parallel review will apply. However, in the *Federal Register* notice, the Agencies request input regarding “[a]t what point during FDA premarket review for **prescription drugs, biologics, and medical devices**, should parallel review begin . . .” (emphasis added). The wording of this question suggests that CMS and FDA are considering the use of parallel review for all regulated products—biologics, drugs, and medical devices.

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