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Prospects Unclear for CMS/FDA Proposed Parallel Review of Medical Products

Overview

Notably absent from last month's Department of Health and Human Services ("HHS") Semiannual Regulatory Agenda[1] was any indication of where the Centers for Medicare and Medicaid Services ("CMS") and the Food and Drug Administration ("FDA") (collectively, "the Agencies") stand with respect to their notice with request for comments, issued last fall, on the proposed parallel review process for medical products.[2] While CMS and FDA officials confirmed that they are currently reviewing comments submitted during the review period, they declined to speculate on when they intend to act. The comments submitted, however, provide insight into industry views on this important issue, including widespread discontent with the approval mechanisms currently available. They also provide a glimpse of the hurdles the Agencies will encounter if and when they proceed with their proposal.

Parallel review would allow CMS to initiate its national coverage determination ("NCD") process during the FDA's premarket review of a medical product. The Agencies have stated that overlapping evaluations by CMS and the FDA could serve to reduce the lag between the FDA's marketing approval or clearance decisions and CMS' national coverage determinations, thereby allowing consumers to access new medical products sooner and creating incentives for investment in innovative medical products. The Agencies proposed to create a voluntary pilot program for parallel review after considering the public's comments on the proposed parallel review.

The Agencies are currently reviewing the 32 comments they received in response to the proposed parallel review initiative. A variety of organizations and individuals—patient advocacy groups, medical device and drug manufacturers, providers, and medical societies—submitted comments. Although commenters generally applauded the Agencies' goals of the parallel review initiative, they expressed grave concerns about possible adverse industry implications. We have undertaken a review of all of the comments submitted and extracted the eight main concerns cited in the comments.

Concerns Highlighted in the Comments

The National Coverage Determination Process is Not the Best Option for Most New Medical Products

The parallel review process, as contemplated in the Federal Register, would involve "CMS begin[ning] its NCD-related review process to determine whether the product is reasonable and necessary for the Medicare population while the FDA is completing its premarket review."[3] Thus, the proposed parallel review process appears to rely solely on the NCD[4] for Medicare coverage determinations. However, as noted in one of the comments, NCDs are just one of three ways Medicare coverage decisions regarding an item or service are made. Many new medical products are covered by local contractors through adjudications of individual claims, and others are covered though local coverage determinations ("LCDs").[5] One commenter, the American Gastroenterological Association, estimated that ninety percent of coverage decisions are made through LCDs.[6]

Multiple comments articulated concerns with the parallel review proposal's emphasis on NCDs, arguing that the local coverage process, not the NCD process, is the most appropriate vehicle to determine coverage for innovative medical products. Several comments stated that if the parallel review process included an automatic pathway to a NCD, the majority of medical product manufacturers would avoid the parallel review process by not participating in the pilot program. This would result in a parallel review program that is not representative of the majority of products under review and calls into question whether the program will address lags between FDA approval and coverage determinations. Many of the comments focused on the fact that a 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, and thus the possibility of a negative NCD poses a great risk to medical products manufacturers that its product would not be covered across the board—forestalling acceptance of innovative technologies on a nationwide level. As an example of the concerns related to NCDs, the Alliance for Regenerative Medicine stated the following:

First, NCD is an inefficient process and often burdensome to sponsors, so greater use of NCDs by CMS—especially for new technologies—will delay patients' access to new therapies. In addition, since a negative determination from the NCD process severely limits a sponsor's ability to get reimbursed, we are concerned that the proposed process could deprive sponsors of market opportunities.[7]

The Medical Device Manufacturers Association ("MDMA") conveyed very similar concerns regarding the parallel review's use of NCDs in its comment. After stating its concerns, the MDMA concluded:

[M]anufacturers understandably are cautious about pursuing coverage through an NCD and prefer to seek coverage from local contractors. The proposed parallel review process would do little to improve access to these companies' innovative technologies because the local coverage process is sufficient. If CMS and FDA develop a parallel review process, CMS must continue to allow local contractors to determine whether to cover products that are not subject to a negative NCD.[8]

Protecting Trade Secrets, Proprietary Information, and Confidential Commercial Information in the Parallel Review Process is Imperative

The NCD process and the FDA premarket review process have different statutory requirements regarding confidentiality. By statute, the NCD process requires that the public be afforded notice and the opportunity to comment prior to implementation of the determination.[9] However, the FDA premarket review protects knowledge of the existence of the application, as well as trade secrets and other proprietary information revealed during the premarket review.[10] Because of the conflicting approaches to confidentiality and protection of trade secrets and proprietary information inherent in the NCD process and the FDA premarket review process, multiple comments expressed confidentiality concerns. For example, AdvaMed, in its comment, stated, "The protection of trade secrets, confidential commercial information, and proprietary information is mandated by statute and regulation, and would likely be difficult to overcome without statutory change or sacrificing essential protections that facilitate the iterative development of critical, often life-saving medical technology."[11]

Blurring of the FDA's and CMS' Statutory Duties

As the Agencies' notice acknowledged, the FDA and CMS have distinct and separate statutory duties and missions. A number of comments communicated the concern that a parallel review process might blur the distinctions of FDA's role in the premarket review process and CMS' role in the NCD process. As stated by one comment, this blurring could lead to CMS influencing or providing input into the FDA's review of products, determinations of safety and efficacy, or orders. According to the comment, any influence exerted by CMS would violate the Food Drug and Cosmetic Act.[12]

To Improve Access to New Technologies, Coding and Reimbursement Issues Need to Be Addressed

A number of the comments pointed to coding and reimbursement decisions as an obstacle to access new medical technology. For example, a comment submitted by MDMA lamented the substantial time required to obtain Healthcare Common Procedure Coding System ("HCPCS") codes and Current Procedural Terminology ("CPT") codes. MDMA's comment then stated, "[I]f [HHS] and its related agencies are to achieve the goal of reducing the time required to bring innovative products to market, it must seriously consider examination of the reimbursement coding systems to identify inefficiencies. . . . HHS should consider a thorough review of both the CPT and HCPCS coding processes."

The Parallel Review Process Must Be Completely Voluntary

The vast majority of the comments emphasized the need for the parallel review process to be completely voluntary, with only the product sponsor having the ability to initiate the request for parallel review. These comments focused on two main concerns with a mandatory parallel review: (1) manufacturers may be forced to reveal sensitive or confidential information; and (2) manufacturers may be forced into the NCD process.

First, manufacturers cited concerns about potentially revealing confidential or proprietary information or trade secrets through the parallel review process. A comment submitted by the Medical Imaging and Technology Alliance reflects this concern: "If CMS and FDA were to allow entities other than the product sponsor to initiate a request for parallel review, the sponsor could be forced to disclose sensitive trade secret information. Such disclosures would discourage investment into research and development and ultimately would deny patients access to beneficial new technologies."[13] Second, other comments related to the voluntariness of the proposed parallel review reflected the concern that initiating the NCD process prematurely or against the will of a medical products manufacturer might result in non-coverage decisions that hinder future research of that technology.[14]

The Coordination of Clinical Trials Needed for Parallel Review May Be Precarious

In their comments some groups cautioned that clinical trials intended to meet the needs of both CMS' NCD process and the FDA's premarket review could be burdensome and prohibitively expensive. For example, several breast cancer advocacy organizations communicated this concern by stating, "If the additional data requirements that CMS needs for making NCD decisions are added to the clinical trial protocols in order to facilitate a parallel review process, the unintended consequence could be increasing the cost of clinical trials, delaying FDA approval and therefore slowing, rather than accelerating, consumer access to new products."[15] MDMA and the Medical Imaging and Technology Alliance articulated similar concerns regarding the consolidation of the FDA and CMS clinical trials. The Medical Imaging and Technology Alliance said, "Satisfying the request of both FDA and CMS could require trials to be larger, designed to evaluate more outcomes and subpopulations, and involve longer follow up periods."[16]

The Parallel Review Initiative Should Be Subject to Notice and Comment Rulemaking

The Agencies had expressed their intention to publish a draft guidance on the parallel review process after reviewing the submitted comments discussed here. However, a number of the comments suggested that notice and comment rulemaking would be the better vehicle for developing the parallel review pilot program. Other comments recommended that, at a minimum, CMS and the FDA should release a detailed draft guidance and allow for public comment prior to implementation of the parallel review pilot program.

CMS and FDA Staffing and Resource Concerns

A number of comments reflected the concern that the FDA and CMS lack the resources and staff in order to efficiently engage in the parallel review of medical products. Further, the comments stated that the lack of resources at both agencies could serve to undermine the parallel review process as a whole. For example, one comment stated:

There is a significant difference in the scale of the two agency's review processes. CMS has only issued 178 National Coverage Decisions since it started this process in 2004 and some of those 178 decisions are repeat reviews of the same technology—up to seven times. The FDA reviews a much greater number of drugs and devices. It is hard to see how CMS could match FDA's volume of reviews. We are concerned that keeping pace with the potential volume of parallel review could strain CMS resources, negatively affecting development of other coverage policies.[17]

Conclusion

Comments in response to the Agencies' parallel review notice indicate significant reservations on behalf of companies, organizations, and patients that would be affected by the proposed parallel review process. There were expressed valid concerns that the agencies are unprepared to handle and coordinate such a process, that parallel review will service to increase the costs of clinical trials, and that parallel review potentially could have a chilling effect on development of innovative technology, in particular.

The final parallel review notice issued by the Agencies will have to address many of the questions currently outstanding with respect to this proposal, such as: will parallel review be more efficient than the current review process? Will the parallel review pilot program be an attractive option for medical device companies? Will parallel review be a short-cut for those technologies currently covered under the umbrella of Coverage with Evidence Development and/or Coverage with Appropriateness Determination? And, finally, what are the risks and benefits of parallel review?

Reed Smith will be closely monitoring the Agencies' actions with respect to the parallel review process in the coming months, and we will report on major developments on our policy blog, www.healthindustrywashingtonwatch.com. We also look forward to working together with our clients to develop and implement strategies to respond to the final parallel review process notice, at such time as one is issued.

Please feel free to contact us if you have questions or if you need additional information.

[1] 76 Fed. Reg. 40052 (July 7, 2011).

[2] See 75 Fed. Reg. 57045 (Sept. 17, 2010).

[3] 75 Fed. Reg. 57045, 57047 (Sept. 17, 2010).

[4] 42 U.S.C. 1395ff(f)(1) defines a NCD as, "a determination by the Secretary with respect to whether or not a particular item or service is covered nationally under title XVIII, but does not include a determination of what code, if any, is assigned to a particular item or service covered under this title or a determination with respect to the amount of payment made for a particular item or service so covered.''

[5] 42. U.S.C. 1395ff(f)(2)(B) defines a LCD as "a determination by a fiscal intermediary or a carrier under part A or part B, as applicable, respecting whether or not a particular item or service is covered on an intermediary-or carrier-wide basis under such parts, in accordance with section 1862(a)(1)(A).''

[6] Comment of American Gastroenterological Association in response to Notice, Request for Comments on Parallel Review of Medical Products, Dec. 16, 2010.

[7] Comment of Alliance for Regenerative Medicine in response to Notice, Request for Comments on Parallel Review of Medical Products, Dec. 16, 2010.

[8] Comment of Medical Device Manufacturers Association, in response to Notice, Request for Comments on Parallel Review of Medical Products, Dec. 16, 2010.

[9] See 42 U.S.C. 1395y(a)(25).

[10] 21 C.F.R. § 814.9.

[11] Comment of AdvaMed, Request for Comments on Parallel Review of Medical Products, Dec. 16, 2010.

[12] Comment of AdvaMed, Request for Comments on Parallel Review of Medical Products, Dec. 16, 2010.

[13] Comment of Medical Imaging and Technology Alliance (MITA), Request for Comments on Parallel Review of Medical Products, Dec. 16, 2010.

[14] Comment of Association of Community Cancer Centers, Request for Comments on Parallel Review of Medical Products, Dec. 16, 2010.

[15] Comment of Breast Cancer Network of Strength, et al.

[16] Comment of MITA, Request for Comments on Parallel Review of Medical Products, Dec. 16, 2010.

[17] Comment of American College of Cardiology, American Society of Echocardiography, Heart Rhythm Society, and Society for Cardiovascular Magnetic Resonance, in response to Notice, Request for Comments on Parallel Review of Medical Products, Dec. 15. 2010.

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