

December 14, 2017

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**Request for Comment Period Extension on Draft Decision Memorandum for Next Generation Sequencing (NGS) for Medicare Beneficiaries with Advanced Cancer (CAG-00450N)**

Dear Ms. Jensen,

The below signed organizations jointly and respectfully request an extension of the comment period on the Centers for Medicare and Medicaid Services' (CMS's) draft coverage decision memorandum for Next Generation Sequencing (NGS) for Medicare Beneficiaries with Advanced Cancer (CAG-00450N). Currently, the comment period for this proposed National Coverage Determination (NCD) is only 30 days, concluding on December 29, 2017. Given the broad nature of the non-coverage provisions of the proposed decision memorandum, and the corresponding impact this decision could have on access to NGS-based testing for Medicare beneficiaries and the development of future genomic-based testing, we request an extension of at least 30 days so that we may assess this complex proposal thoroughly before providing detailed comments. As explained below, CMS is not barred by statute from providing a comment period greater than 30 days for stakeholders to comment on a proposed NCD.

In the proposed decision memorandum, CMS lists several potential criteria for the coverage of NGS-based tests in advanced cancer that would prohibit coverage for certain current and emerging applications of NGS testing holding great promise for Medicare beneficiaries. Additionally, CMS asks for "substantive input from stakeholders" on five broad questions that call for detailed explanation of how laboratories develop and validate laboratory tests. In many of these questions, CMS requests that arguments be well-supported by peer-reviewed literature. We believe that the 30-day comment period is insufficient to provide comments on all the significant issues CMS raised in draft NCD, which will be useful to the agency as it considers whether to finalize the draft NCD.

Based on the reasons set forth below, CMS can extend the comment period for this proposed NCD without concern about violating the statutory timeframe. Social Security Act section 1862(l) requires CMS to issue a draft NCD within 6 months of a request for an NCD, followed by a 30-day comment period and a 60-day decision period. CMS could extend the comment period by 30-45 days and still conclude the NCD review process on time and consistent with the statutory requirements. We note that the statute requires that CMS "shall provide a 30-day period for public comment"<sup>1</sup> - it does not prohibit CMS from accepting

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<sup>1</sup> See Social Security Act section 1862(l)(3)(B).

comments for a longer period of time. If CMS extends the comment period to 60-75 days in total, and uses the 60-day decision period, it could still complete the NCD process in compliance with the statute.

The statute demonstrates Congress' understanding of the importance of public input into CMS's coverage decisions, while also requiring CMS to act promptly on requests for NCDs. Ordinarily, the statute's timeline would allow interested parties up to 7 months to study and evaluate the issues involved in the proposed NCD. This might be sufficient time for meaningful comments when an NCD request is externally generated and the public has been involved in the process from the beginning. However, CMS initiated this NCD process through an internal request in association with a parallel review with the Food and Drug Administration (FDA), and the agency should take care to ensure that all affected parties have adequate time to assess the draft NCD.

Additionally, the statute prescribes a specific time-period in instances where the agency has received a request for an NCD. Section 1862(l)(2) is clearly headed by "TIMEFRAME FOR DECISIONS ON REQUESTS FOR NATIONAL COVERAGE DETERMINATIONS," and the statutory schedule for both comments and finalization is premised on "...the case of a request for a national coverage determination." CMS notes in the proposed decision memorandum that it received a "formal request from Foundation Medicine, Inc. to initiate a national coverage analysis (NCA) for comprehensive genomic profile testing with F1CDx, a next generation sequencing comprehensive genomic profile (CGP) for solid tumors," on November 17, 2017. As such, CMS is bound by the statute to adhere to a prescribed comment timetable and final decision only with respect to this request. CMS did not receive a "request" to establish a broad-based policy for coverage of NGS, so the agency is neither limited in its comment period – nor in the finalization period – with respect to the broader policy.

Finally, we note that although CMS has extended this NCA beyond the parallel review of only the Foundation One Companion Dx, FDA has yet to post any of the summary documents relating to the approval under the Premarket Approval (PMA).<sup>2</sup> Despite the fact that it is nearly half-way through the 30-day comment period provided by CMS, stakeholders still do not have access to the regulatory documents used as the basis for FDA's approval under the parallel review that was responsible for CMS's initiation of this NCA.

In the interests of allowing meaningful public comment, we respectfully request that CMS extend the comment period by at least 30 days. The additional time would provide stakeholders the opportunity to develop thoughtful comments supported by peer-reviewed literature, in order to assist CMS with development of a high-quality policy that meets the needs of patients, health care practitioners, and the laboratory community. Even with a 45-day extension of the public comment period and a 60-day review of stakeholder input, CMS could

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<sup>2</sup> At the time of submission of this letter to CMS, the FDA website expected to include the regulatory documents providing that agency's evaluation of the Foundation One Companion Dx test. See <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P170019>.

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still finalize the draft NCD within statutorily prescribed timeframe. Thank you for your consideration of our request.

Sincerely,

Association of American Medical Colleges

American Clinical Laboratory Association

Association for Molecular Pathology

Association for Pathology Chairs

American Society for Clinical Pathology

California Clinical Laboratory Association

College of American Pathologists