The Parallel Review program allows CMS and FDA to review information about medical devices concurrently, rather than sequentially, while continuing to make their premarket review and coverage decisions consistent with their respective statutory authority. The agencies have announced their intention that the pilot program, which began in October 2011, will be fully implemented and extended indefinitely. As such, the agencies are seeking nominations by manufacturers of innovative devices to participate in the program (Notice, 81 FR 73113, October 24, 2016).

Background. The Parallel Review program is intended to reduce the time between the FDA’s marketing approval or the FDA’s granting of a de novo request and Medicare coverage decisions through CMS’ National Coverage Determination (NCD) process. Because CMS usually begins its NCD decision making process after they have been approved or cleared by FDA, the Parallel Review program will assist in ensuring prompt and efficient patient access to safe and effective and appropriate medical devices for the Medicare population.

The agencies announced their intention to initiate a Parallel Review pilot program on September 17, 2010 (75 FR 57045). On October 11, 2011, the agencies provided notice (76 FR 62808) of the procedures for voluntary participation in the pilot program as well as the guiding principles they intended to follow during the program. On December 18, 2013, the agencies extended (78 FR 76628) the duration of the pilot program for an additional two years.

Lessons learned. During the Parallel Review pilot program the agencies learned that the feedback that manufacturers receive from both agencies at the pivotal clinical trial design stage can assist manufacturers in designing pivotal trials that can answer both agencies’ evidentiary questions. In addition, they found that concurrent review by the agencies of clinical evidence can reduce the time from FDA premarket approval or the granting of a de novo request to an NCD.

Process. The program has two stages: (1) the pivotal clinical trial design development stage, and (2) the concurrent evidentiary review stage. The manufacturer should submit a request for parallel review prior to the start of the first stage, which indicates their interest in the program and includes certain pertinent information. Upon completion of the pivotal trial and submission of an original or supplemental premarket approval application, or a de novo request, the agencies intend to review the pivotal clinical trial evidence concurrently.

Manufacturers and each agency have the option to withdraw from the Parallel Review program until CMS opens the NCD by posting a tracking sheet. Once a tracking sheet is posted, CMS must complete the statutorily defined NCD process.