

HCFA New Technology IOL Regulation

The Health Care Financing Administration (HCFA), which administers the Medicare program, has a new regulation that allows for the designation of certain IOLs as New Technology IOLs (NTIOLs). A sponsor must submit an application to HCFA requesting NTIOL designation and if granted, HCFA will reimburse \$50 more per lens for five years.

The NTIOL regulation states that a lens is a NTIOL if FDA has approved specific claims of clinical advantages or superiority compared to existing IOLs. The following excerpt is from the regulation¹:

"New technology IOL means an IOL that HCFA determines has been approved by the FDA for use in labeling and advertising the IOL's claims of specific clinical advantages and superiority over existing IOLs with regard to reduced risk of intraoperative or postoperative complication or trauma, accelerated postoperative recovery, reduced induced astigmatism, improved postoperative visual acuity, more stable postoperative vision, or other comparable clinical advantages.

New technology subset means a group of IOLs that HCFA determines meet the criterion for being treated as new technology IOLs and that share a common feature or features that distinguish them from other IOLs. For example, all new technology IOLs that are made of a particular bioengineered material could comprise one subset, while all that rely on a particular optical innovation could comprise another."

We anticipate that sponsors will be designing studies to support new marketing claims that they will also use to apply to HCFA for NTIOL designation. In some situations, such as claiming reduced incidence of PCO, demonstrating superiority to all IOLs is difficult. The question of when a sponsor has shown superiority to all IOLs is one for which Panel input is valuable.

¹Federal Register: June 16, 1999 (Volume 64, Number 115); Medicare Program; Adjustment in Payment Amounts for New Technology Intraocular Lenses Furnished by Ambulatory Surgical Centers. Final rule.