Registry Data Are Best for PQRI

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BALTIMORE — Outcomes registries, not claims data, should be the base for the Physician Quality Reporting Initiative next year, physicians and their representatives said at a forum held in May by the Centers for Medicare and Medicaid Services.

CMS officials said they are gathering comments on how to evolve from claims-based information to a registry model, in an effort to prevent duplicative efforts to collect data and to encourage quality improvement. The agency's final recomendations will be published in the Federal Register in mid-August as a proposed set of 2008 reportable measures, agency officials said.

PQRI is a hot topic among physicians. According to a Department of Health and Human Services spokeswoman, more than 600 people attended the forum via conference call. The initiative was mandated as part of the Tax Relief and Health Care Act of 2006. Beginning in July, physicians can take part in the initiative by reporting on specialty-specific measures. This year, CMS has listed 74 measures (posted at www.cms.hhs.gov/PQRI).

To participate, physicians submit data on those measures through December on at least 80% of their cases. Those who participate will get a bonus lump-sum payout of 1.5% of claims submitted, some time in mid-2008.

Many physicians already report on such measures to specialty societies.

The longest-running registry is maintained by the Society of Thoracic Surgeons. The 17-year-old registry contains more than 3 million records, Dr. Jeffrey Rich of the STS said at the forum. The STS supports the PQRI effort, but "we feel that it must go farther, and we feel that can be accomplished through the use of registries."

This year, PQRI is structured to collect data on processes, not outcomes, he said. Registries allow for the collection of clinical data on patient outcomes, which is more useful for quality improvement, Dr. Rich said.

STS suggested that outcomes measures should be vetted through groups such as the American Medical Association's Physician Consortium for Performance Improvement and the AQA (formerly the Ambulatory Care Quality Alliance). Measures that cut across disciplines should be harmonized, preferably by the National Quality Forum, he said. And input standards should be established to ensure that the data cover all patients, not just a random sample, Dr. Rich said. Finally, registries should be subject to validation and an audit mechanism.

CMS officials also heard about registries developed by the American Osteopathic Association, the Wisconsin Collaborative for Healthcare Quality, users of GE Healthcare's electronic medical records, the American Medical Group Management Association, and the American Society of Plastic Surgeons.

The ASPS launched its Tracking Operations and Outcomes in Plastic Surgery (TOPS) registry in 2002. TOPS collects data from all surgical settings, including office-based procedures. About 10% of the organization's 6,000 members use TOPS now, said an ASPS representative at the forum. The ASPS is currently redesigning the registry in the hopes that it will integrate more smoothly with PQRI, she said.

Jean Harris of the American College of Surgeons said that organization is exploring registry development through the Surgical Quality Alliance.

The American Board of Neurological Surgery has developed 15 procedure-specific outcomes measures that are available online, said Dr. Robert Harbaugh of the American Association of Neurological Surgeons. The ABNS envisions using the measures to teach neurosurgery residents how to collect outcomes data and to use the data for quality improvement, for neurosurgeons to prepare for board certification, and as part of the maintenance of certification process.

In 2006, the American Board of Internal Medicine began requiring internists to begin using Practice Improvement Modules (PIMs) in order to maintain certification. With PIMs, physicians enter medical data about patients, and then receive reports back from ABIM, which they are supposed to analyze and use to develop a self-improvement plan.

More than 5,000 physicians completed a PIM in 2006, and 5,000 more are currently working on PIMs, Dr. Cary Sennett, ABIM senior vice president of strategy and clinical analytics, said at the forum.

Aetna, UnitedHealthcare, Humana and several regional Blue Cross and Blue Shield plans have recognized PIMs as fulfilling quality improvement criteria, said Dr. Sennett, who added that ABIM supported the PQRI effort.

The American College of Physicians was due to make a statement at the forum, but a representative on the conference call said the group decided it was not ready to share its thoughts on registries and PQRI yet. ■

Medicare Proposes Policy Revisions For Clinical Trials

Future clinical trials may have to conform to several new procedural and reporting requirements in order for Medicare beneficiary participants to be eligible for reimbursement, if revisions to the Clinical Trial Policy national coverage determination are implemented.

Changes proposed by the Centers for Medicare and Medicaid Services would include:

- ► Requiring all trials to be registered on the National Institutes of Health ClinicalTrials.gov Web site before enrollment begins.
- ► Requiring investigators to publish their results.
- ► Requiring the study to explicitly discuss inclusion criteria and relevant subpopulations (as defined by age, gender, race/ethnicity, socioeconomic, or other factors) in the study protocol.
- ► Adding Food and Drug Administration postapproval studies and coverage with evidence development (CED) to studies that would qualify under this policy.
- ► Paying for investigational clinical services if they are covered by Medicare outside the trial or required under CED through the national coverage determination (NCD) process.
- ► Expanding the agencies that can deem whether a trial has met the general policy standards to include all Department of Health and Human Services agencies, the Veterans Administration, and the Department of Defense.

The 30-day public commentary period began in April. The CMS will review all public comments and suggestions and incorporate them into the final published NCD no later than 60 days after the end of the comment period, and the revised policy will be effective with that publication.

The Clinical Trial Policy (to be renamed the Clinical Research Policy) was first developed in 2000 to allow Medicare to pay for certain items and services for Medicare beneficiaries involved in clinical trials.

Further details are available from the CMS coverage Web site at www.cms.hhs.gov/mcd/viewdraftdecisionmemo.asp?id=186.

—Mark S. Lesney