

Why GAO Did This Study

The American Taxpayer Relief Act of 2012 instructed HHS to establish a new program to designate “qualified” CDRs—entities that would work with physicians treating Medicare patients to collect clinical information and use it to improve the quality and efficiency of care. The act also mandated GAO to report on the potential for CDRs to improve quality and efficiency.

This report examines (1) improvements demonstrated by CDRs in quality and efficiency of care, (2) HHS’s plans for requirements and oversight for qualified CDRs, (3) actions HHS could take to facilitate the development of qualified CDRs, and (4) actions HHS could take to facilitate CDRs’ use of health IT. GAO reviewed relevant studies and documents, and interviewed HHS and CDR officials. GAO also convened an expert meeting with the assistance of the Institute of Medicine and synthesized input from experts and other sources to assess the likely effect of potential program requirements, approaches to oversight, and other actions HHS could take.

What GAO Recommends

GAO recommends that HHS (1) focus its requirements for qualified CDRs on improving quality and efficiency, (2) require qualified CDRs to demonstrate improvement in quality and efficiency, (3) draw on expert judgment to monitor qualified CDRs, (4) reduce barriers to the development of qualified CDRs, and (5) include, if feasible, key data elements needed by qualified CDRs in its requirements under the EHR incentive programs. HHS agreed with GAO’s recommendations.

View [GAO-14-75](#). For more information, contact Linda T. Kohn at (202) 512-7114 or kohnl@gao.gov.

CLINICAL DATA REGISTRIES

HHS Could Improve Medicare Quality and Efficiency through Key Requirements and Oversight

What GAO Found

Clinical data registries (CDR) have demonstrated a particular strength in assessing physician performance through their capacity to track and interpret trends in health care quality over time. Studies examining results reported by several long-established CDRs demonstrate the utility of CDR data sets for analyzing trends in both outcomes and treatments. CDR efforts to improve outcomes typically involve a combination of performance improvement activities including feedback reports to participating physicians, benchmarking physician performance relative to that of their peers, and related educational activities designed to stimulate changes in clinical practice. Studies GAO reviewed provided less insight on ways to improve the efficiency of care.

The Department of Health and Human Services’ (HHS) plans for implementing the qualified CDR program offer little specificity and provide substantial leeway for CDRs seeking to become qualified. According to officials, HHS plans to have its program requirements and structure evolve over time, and a key question is the extent to which this evolutionary process will focus on harnessing the potential of CDRs to promote quality and efficiency. GAO’s synthesis of input from experts and from other relevant sources identified several key requirements that would make it more likely that qualified CDRs promote improved quality and efficiency, which HHS’s current plans for the program would do little to address. These requirements include directing CDRs to focus data collection on performance measures that address the key opportunities for improvement in quality and efficiency for each CDR’s target population and requiring CDRs to demonstrate improvement over time on the quality and efficiency measures that they collect. In addition, effective oversight of these requirements depends on expert judgment to take account of variation among CDRs in their circumstances and opportunities for improvement.

Experts indicated that HHS can also help qualified CDRs to improve the quality and efficiency of care provided to Medicare patients by taking actions that could reduce potential barriers to the development of qualified CDRs, such as concerns about complying with privacy regulations and the difficulty of funding CDRs. GAO’s synthesis of input from experts and from other relevant sources identified several specific actions that HHS could take. They include developing guidance to clarify federal privacy requirements for physicians participating in CDRs and testing one or more models of shared savings between Medicare and qualified CDRs that achieve reduced Medicare expenditures with improved quality of care.

In addition, input from experts and other relevant sources suggests that HHS can take actions to facilitate CDRs’ use of health information technology (IT). According to CDR officials, some CDRs have developed approaches to electronically capture and transmit large amounts of detailed clinical data from a wide variety of electronic health record (EHR) systems. CDRs could benefit from new IT standard setting that focuses on data elements needed for the measures that CDRs collect. One way HHS can influence whether EHR vendors use IT standards to design EHR systems that are compatible with CDR needs is through its setting of meaningful use requirements in its EHR incentive programs.