

Why GAO Did This Study

In 2009, the Department of Veterans Affairs (VA) spent nearly \$4 billion on prescriptions for veterans. In general, VA provides drugs on its national formulary. However, all VA medical centers must have a nonformulary drug request process that is overseen by their regional Veterans Integrated Service Network (VISN). This report responds to a House Committee on Appropriations report directing GAO to review VA's formulary process and to an additional congressional request. Specifically, GAO reviewed (1) the process VA uses to review drugs for its national formulary, (2) the approaches VISNs and medical centers take to implementing the nonformulary drug request process, (3) the extent to which VA ensures the timely adjudication of nonformulary drug requests, and (4) the mechanisms VA has in place to obtain beneficiary input on the national formulary and make the drug review process transparent. GAO reviewed VA policy guidance and VA's pharmacy-related information technology (IT) initiatives, analyzed 2008 and 2009 drug review data and 2009 nonformulary drug request data, and interviewed VA officials from the national level, each VISN, and a judgmental sample of four medical centers.

What GAO Recommends

GAO recommends that VA establish additional mechanisms to ensure nonformulary drug requests are adjudicated in a timely fashion. VA concurred with this recommendation.

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VA DRUG FORMULARY

Drug Review Process Is Standardized at the National Level, but Actions Are Needed to Ensure Timely Adjudication of Nonformulary Drug Requests

What GAO Found

VA uses a standardized process to review drugs for its national formulary that is coordinated at the national level by its Pharmacy Benefits Management Services (PBM). The Chief Consultant from VA's PBM told us that most drug reviews are initiated in response to FDA's approval of drugs for use on the market. To begin the process of deciding whether to include a drug on the national formulary, PBM develops evidence-based drug monographs that include information on safety, efficacy, and cost. PBM seeks comments on these monographs from VISN and medical center staff and, when appropriate, subject-matter experts. Once a monograph is complete, PBM sends it to its Medical Advisory Panel and the VISN Pharmacist Executive Committee, which review the monograph and vote on whether to add the drug to the national formulary. According to information provided by PBM, reviews for a majority of the drugs VA considered for addition to the national formulary in 2008 and 2009 were completed within a year of FDA approval, but there were a number of factors, such as safety concerns, that caused some to take longer.

VISNs and medical centers vary in how they implement the nonformulary drug request process, including how they adjudicate nonformulary drug requests, collect and report required data to VA's PBM, and address appeals of denied requests. GAO found that IT enhancements could help facilitate more consistent implementation of the process. Although VA is working on replacing its pharmacy IT system, officials could not tell GAO whether components that would support the nonformulary drug request process will be implemented.

VA requires that nonformulary drug requests be adjudicated within 96 hours, but it is unable to determine the total number of adjudications that exceed this standard due to limitations in the way data are collected, reported, and analyzed. While the total number of nonformulary drug request adjudications that exceed 96 hours is unknown, GAO found that data reported to VA's PBM on quarterly average adjudication times for medical centers are sufficient to demonstrate that not all requests are adjudicated within this time frame. Additionally, PBM does not have the framework in place to ensure that appeals of denied nonformulary drug requests are resolved in a timely fashion.

VA obtains input from beneficiaries on the national formulary mainly through Veterans Service Organization meetings and complaints, though some VISNs have taken additional steps to seek this input. Officials from VA's PBM told GAO that they make the drug review process transparent to veterans through national formulary information available on PBM's Web site, and some VISN and medical center officials described undertaking other activities to educate beneficiaries. At the national level, VA officials are considering options for increasing beneficiary input on the national formulary and improving the transparency of the drug review process, and most VISN and medical center officials told us there could be benefit to doing so.