



Government Affairs Division

Issue Paper

PDUFA Reauthorization: Opportunity to Improve Continuity of Care For Patients Treated with High-Risk Drugs

Background:

A restricted drug distribution system (RDDS) is a program established by a drug manufacturer to limit access to a particular drug. Such programs are developed for many reasons, most importantly to ensure that drugs with very high risks are prescribed, dispensed and administered safely. Legislation that increases FDA's post-marketing surveillance authorities may result in an increased number of RDDS programs. While these systems are necessary in appropriate circumstances to protect patients, there are many challenges associated with their administration, especially in the hospital setting, which compromise the quality of patient care.

ASHP believes that the current debate on drug safety and reauthorization of the Prescription Drug User Fee Act provides a unique opportunity to improve elements of FDA's oversight of these programs, improving patient care and reducing unnecessary burdens on the health care system.

There are currently more than 20 RDDS programs in the United States, all having different registration processes and requirements for providers and patients. Several of these programs also require that drugs be obtained through a specialty pharmacy. Some RDDS drugs include:

- Clozaril (clozapine)- This drug is a second generation anti-psychotic agent and is used to treat severe schizophrenia. The "Registry Program" requires a lab test prior to dispensing in order to detect a decrease in white blood cell count.
- Tikosyn (dofetilide)- This drug is used to treat abnormal heart rhythms but is closely monitored to prevent a serious heart arrhythmia, which could be potentially life threatening. The T.I.P.S. Program requires use of a specialty pharmacy.
- Thalomid (thalidomide)- This drug treats lesions associated with erythema nodosum leprosum (ENL), a complication of Hansen's Disease (leprosy). The drug can cause birth defects and therefore the S.T.E.P.S. Program requires a pregnancy test.

These programs all require that physicians and pharmacists be registered. The Clozaril and Thalomid programs also require patient registration. Each drug has a different registration process. Wide variation in registration requirements creates confusion and burden on the health care system and can have a negative impact on patient care, as discussed below.

ASHP Member Survey

ASHP recently conducted a survey of its members who have experience with RDDS to better understand what hospital pharmacists and their patients are experiencing with regard to these programs. ASHP received 521 responses from hospitals and health-systems nationwide with 49 states represented. Respondents stated:

- RDDS programs compromise timely patient access to drugs: frequently (23%) and occasionally (67%).
- RDDS programs compromise continuity of care: frequently (20%) and occasionally (62%).
- Sixty-seven percent of respondents believe that it is possible to standardize some aspects of RDDS programs.

For more information:

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ASHP Policy Requests: We urge members of the HELP Committee to include language in the Prescription Drug User Fee Act reauthorization that would require the FDA Drug Safety and Risk Management Advisory Committee to analyze current FDA standards and recommend new policy in several key areas related to RDDS including:

- Feasibility of standardizing basic elements of all programs (ie, processes, procedures, registration forms, etc.),
- Ensuring timely access to drugs for patients,
- Eliminating continuity of care problems, and
- Permitting exceptions from various RDDS program registration rules for those practitioners that meet predetermined agency standards and requirements.

We also ask that the Committee include provisions in the reauthorization that would require FDA, in partnership with professional organizations, to research how well existing and new RDDS are achieving their goals.

If you have additional questions about this issue, please contact Mara Baer, ASHP Director of Federal Legislative Affairs at: 301-664-8710 or mbaer@ashp.org or Brian Meyer, Director Government Affairs at bmeyer@ashp.org.