DEA REGISTRATION FEES FACT SHEET

Summary

- On April 16, 2012,the Drug Enforcement Administration (DEA) will implement an adjustment to the fees it charges to DEA registrants. For the vast majority of registrants (healthcare practitioners), the increase will be $5 per month over a three-year registration period.

- The fees collected by the DEA are used to fund the activities associated with DEA's Diversion Control Program, and DEA is statutorily mandated to recover the full cost of this program through the fees it collects from DEA registrants.

- This fee adjustment reflects the lowest percentage increase since DEA began recouping its diversion-related operational funds from registrants.

- DEA registrants include entities such as controlled substance and listed chemical manufacturers, importers, exporters, distributors, and pharmacies, hospitals, physicians, nurse practitioners, and physician's assistants.

The Diversion Control Program

- The citizens and residents of the United States bear an enormous cost from the abuse of controlled substance pharmaceuticals. According to research published in *The Clinical Journal of Pain*, the economic costs associated with the nonmedical use of prescription opioids increased from $8.6 billion in 2001 to $53.4 billion in 2006, which includes costs to the health care and criminal justice systems as well as costs to the workplace from lost productivity.

- The Diversion Control Program's (DCP's) enforcement activities are designed to reduce the supply of dangerous controlled substance pharmaceuticals and listed chemicals available for abuse by maintaining the integrity of the closed system of distribution for controlled substances.

- These efforts are more important now than ever: Several national studies demonstrate that prescription drug abuse is on the rise, and a rise in abuse imposes significant costs throughout the system and on society. According to the 2010 National Survey on Drug Use and Health (NSDUH), seven million Americans were current (past month) non-medical users of psychotherapeutic drugs. This statistic is significantly higher than what was reported in 2008 (6.2 million more persons, or an increase of 12 percent). Over three-quarters of that number, 5.1 million Americans, reported non-medical use of pain relievers.

- The consequences of prescription drug abuse are seen in the data collected by the Substance Abuse and Mental Health Services Administration (SAMHSA) on emergency room visits. According to the latest data, SAMHSA estimates that of the 4.6 million emergency department visits in 2009 associated with drug use, about 1.2 million visits involved the non-medical use of pharmaceuticals. Emergency department visits involving non-medical use of pharmaceuticals (misuse or abuse) almost doubled between 2004 and 2009, representing a 98.4 percent increase. About half of the 2009 emergency department visits related to abuse or misuse of

pharmaceuticals involved painkillers and more than one-third involved drugs to treat insomnia and anxiety.

- The DCPaddresses the supply side of these issues by carrying out the mandates of the Controlled Substances Act and its regulations to prevent, detect, and eliminate the diversion of controlled substances and listed chemicals into the illicit market while ensuring a sufficient supply of controlled substances and listed chemicals for legitimate medical, scientific, research, and industrial purposes.

- The DCP is responsible for registering and regulating more than 1.4 million registrants who handle, dispense or prescribe controlled substances or listed chemicals. The program also maintains information technology infrastructures used by registrants to submit new or renewal applications, order controlled substance pharmaceuticals, and submit required reports to DEA in electronic format. The DCP employs more than 1,400 personnel who, in addition to registration activities, conduct administrative, civil and criminal investigations that expose and obstruct unlawful diversion activities. The DCP is also responsible for managing and issuing quotas, and conducting rulemaking and scheduling actions.

Efforts to Minimize Costs

- DEA recognizes that any increase in fees affects the registrant community. DEA has been, and continues to be, fiscally responsible and attempts to minimize costs while implementing programs to address the diversion of controlled substances and listed chemicals.

- Although the last fee adjustment was calculated to fund operations during Fiscal Years 2006-2008, by implementing efficiencies and other cost-management efforts DEA was able to retain the prior fees for more than five years. During that time, the DCP significantly increased its activities in response to the prescription drug abuse epidemic across the United States. The new fee schedule will allow DEA to sustain existing and enhanced operations and employ additional personnel in support of important program initiatives during Fiscal Years 2012-2014.

- A general description of DCP current and anticipated activities are outlined in the NPRM and Final Rule (which can be found on www.deadiversion.usdoj.gov), such as initiatives to strengthen and expand Tactical Diversion Squads and diversion groups, as well as increased regulatory oversight and registrant education.

Procedure to Adjust Fees

- DEA proposed adjusting the 2006 registration fees by soliciting public comment through a Federal Register notice published on July 6, 2011. DEA carefully considered all comments submitted during the 60-day comment period, and provided responsive analysis to those comments in the Final Rule.

- The final fees to be implemented are slightly lower than proposed in July, 2011. The notice, final rule, and all of the supporting documents, may be found on DEA's website, www.deadiversion.usdoj.gov.

- DEA continually monitors the anticipated budget and collections to determine whether the registration fees need to be adjusted. The budgets are key factors in calculating fees, as monies may be paid from the Diversion Control Fee Account only in accordance with the budget requests or after notification to the Committees on Appropriations of the House of Representatives and the Senate.

- The registration fees were calculated through these five major steps:

    1. Estimate program obligations for FY 2012, FY 2013, and FY 2014.
    2. Determine the total amount of registration fees that need to be collected over the three year period by applying additional factors such as:
        a. Mandated $15 million transfer to the U.S. Treasury
        b. Maintenance of the Operational Continuity Fund (OCF) balance
        c. Combat Methamphetamine Epidemic Act (CMEA) self-certification fee collections
        d. Other collections from the sale of official government vehicles
        e. Recoveries from the deobligation of prior year obligations
    3. Estimate the total number of registration fee transactions by business activity, new and renewal, over the three year period.
    4. Apply the weighted ratio to the total required collections and the total number of registrations.
    5. Finally, apply these fees to the estimated number of registrations by business activity for each of the three years to determine projected collections per year and estimated OCF balance, based on an estimated fee collection date.

Selected Calculation Method

- A weighted ratio method has been used since inception of the fee. Under this method, a base rate is calculated and then registrant categories are assigned a weighted value, e.g., 1.0 for researchers, 3.0 for dispensers, 6.25 for distributors, and 12.5 for manufacturers.

- In the NPRM and Final Rule, DEA supported its selection of the weighted ratio method by explaining that, historically, registration and other costs are greatest for manufacturers because of the risk and consequences of diversion associated with the quantity and quality of controlled substances at this point in the closed system, and this method produced a result that was reasonable for all registrants in terms of absolute amount of increase, the change in fee as a percentage of revenue, and the relative increase across registrant groups.

- DEA analyzed several alternate methodologies for calculating fees, and demonstrated that those alternatives would have resulted in unfair and unreasonable fees. For example, under one option, manufacturers would incur an increase of $15,000 annually over the current registration fee of $2,293, while practitioner fees would increase by $48 annually. Under another option, manufacturers and distributors would experience a reduction in fees by 89% and 78% respectively, while practitioners would experience a 34% increase in fees.

- The weighted ratio methodology was the only method that yielded a fair and reasonable result for all registrants.

New Fee Schedules

The new fees are reflected in the below chart:

Registrants on Three Year Registration Cycle

Registrant Class/Business	Current Three YearFee*	New Three Year Fee*	Difference Per Year
Pharmacy	$551	$731	$60
Hospital/Clinic	$551	$731	$60
Practitioner	$551	$731	$60
Teaching Institution	$551	$731	$60
Mid-Level Practitioner	$551	$731	$60

*Pharmacies, hospitals/clinics, practitioners, teaching institutions, and mid-level practitioners register for a three-year period. The current three-year registration fee is $551. The new fee for the threeyear registration period would be $731.The three year difference is $180, or an annual difference of $60.

Registrants on Annual Registration Cycle

Registrant Class/Business	Current Annual Fee	New Annual Fee	Difference
Researcher/Canine Handler	$184	$244	$60
Analytical Lab	$184	$244	$60
Maintenance	$184	$244	$60
Detoxification	$184	$244	$60
Maintenance and Detoxification	$184	$244	$60
Compounder/Maintenance	$184	$244	$60
Compounder/Detoxification	$184	$244	$60
Compounder/Maintenance/ Detoxification	$184	$244	$60
Distributor (chemical and controlled substances)	$1,147	$1,523	$376
Reverse distributor	$1,147	$1,523	$376
Importer (chemical and controlled substances)	$1,147	$1,523	$376
Exporter (chemical and controlled substances)	$1,147	$1,523	$376
Manufacturer (chemical and controlled substances)	$2,293	$3,047	$754

Fee-Exempt Registrants

- Exempt from the payment of registration fees are any hospital or other institution that is operated by an agency of the United States, of any State, or any political subdivision or an agency thereof. Likewise, an individual who is required to obtain a registration in order to carry out his/her duties as an official of a federal or State agency is also exempt from registration fees.

- Approximately, 96,000 individual and institutional registrants (7% of all registrants)are exempt from registration fees.Fee exempt registrants are not affected by the fees. See 21 CFR 1301.21 for complete fee exemption requirements.