Cynthia Marcotte Stamer, P.C.
SOLUTIONS LAWYER™

Primary Office
16633 Dallas Parkway, Suite 600
Addison, Texas 75001
Primary Telephone: (214) 538.8297
24-Hour Telephone: (469) 767.8872

Helping Management Manage

Plano/Mail Room
3948 Legacy Drive
Suite 106, Box 397
Plano, Texas 75023

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Guidance For 2012 Branded Prescription Drug Fee Filings Released

The Internal Revenue Service (IRS) has released guidance about the branded prescription drug fee applicable to covered entities engaged in manufacturing or importing branded prescription drugs for the 2012 fee year.

Notice 2011-92 provides guidance on related to (1) the submission of Form 8947, "Report of Branded Prescription Drug Information," (2) the time and manner for notifying covered entities of their preliminary fee calculation, (3) the time and manner for submitting error reports for the dispute resolution process, and (4) the time for notifying covered entities of their final fee calculation. It is scheduled for publication in Internal Revenue Bulletin 2011-48 on November 28, 2011.

The annual branded prescription drug fee requirements were enacted under Section 9008 of the Patient Protection and Affordable Care Act, Public Law 111-148 (124 Stat. 119 (2010)), as amended by section 1404 of the Health Care and Education Reconciliation Act of 2010, Public Law 111-152 (124 Stat. 1029 (2010)) (Affordable Care Act). The Branded Prescription Drug Fee Regulations in 26 C.F.R. Part 51, detail the method for calculating each covered entity's annual fee and terms for the administration of the fee

As part of these requirements, Internal Revenue Code § 51.3T provides that each covered entity may submit annually a completed Form 8947, "Report of Branded Prescription Drug Information" by the applicable annual deadline set by the IRS. The form solicits information from covered entities on National Drug Codes, orphan drugs, designated entities, rebates, and other information specified by the form or its instructions. Notice 2011-92 sets December 15, 2011 as the deadline for submitting the Form 8947 for the 2012 fee year.

Sections 51.6T requires the IRS make and notify each covered entity of the preliminary fee calculation for each covered entity each year. According to Notice 2011-92, the IRS will mail each covered entity a paper notice of its preliminary fee calculation for the 2011 fee year by April 2, 2012. This mailing will include a National Drug Code (NDC) attachment (NDC attachment) that lists the covered entity's NDCs and the sales data reported to the IRS by each government program pursuant to § 51.4T.

Section 51.7T provides that upon receipt of its preliminary fee calculation, each covered entity will have an opportunity to dispute this calculation by submitting to the IRS an error report with prescribed information within the timeframe set by the IRS. Sections 51.7T(b) and (c) set out the information that a covered entity must submit to support each asserted error. Notice 2011-92 states a covered entity wishing to submit an error report regarding its preliminary fee calculation for the 2012 fee year must use a template on a CD-ROM that will accompany the preliminary fee calculation and mail the error report by May 16, 2012.

Notice 2011-92 affirms that in accordance with § 51.8T(a), the IRS will notify each covered entity of its final fee calculation for 2012 by August 31, 2012. In accordance with §51.8T(c), each covered entity must pay this fee by September 30, 2012.

For More Information Or Assistance

If you need assistance reviewing or tightening your policies and procedures, conducting training or audits, responding to or defending an investigation or other enforcement action or with other health care related risk management, compliance, training, enforcement or management concerns, the author of this update, attorney Cynthia Marcotte Stamer, may be able to help. Vice President of the North Texas Health Care Compliance Professionals Association, Past Chair of the ABA Health Law Section Managed Care & Insurance Section and the former Board Compliance Chair of the National Kidney Foundation of North Texas, Ms. Stamer has more than 24 years experience advising health industry clients about these and other matters. Her experience includes advising hospitals, nursing home, home health, rehabilitation and other health care providers and health industry clients to establish and administer compliance and risk management policies; prevent, conduct and investigate, and respond to peer review and other quality concerns; and to respond to Board of Medicine, Department of Aging & Disability, Drug Enforcement Agency, OCR Privacy and Civil Rights, HHS, DOD and other health care industry investigation, enforcement and other compliance, public policy, regulatory, staffing, and other operations and risk management concerns.

A popular lecturer and widely published author on health industry concerns, Ms. Stamer continuously advises health industry clients about compliance and internal controls, workforce and medical staff performance, quality, governance, reimbursement, and other risk management and operational matters. Ms. Stamer also publishes and speaks extensively on health and managed care industry regulatory, staffing and human resources, compensation and benefits, technology, public policy, reimbursement and other operations and risk management concerns. Her presentations and programs include How to Ensure That Your Organization Is In Compliance With Regulations Governing Discrimination, as well as a wide range of other workshops, programs and publications on discrimination and cultural diversity, as well as a broad range of compliance, operational and risk management, and other health industry matters.

Her insights on these and other related matters appear in the Health Care Compliance Association, Atlantic Information Service, Bureau of National Affairs, World At Work, The Wall Street Journal, Business Insurance, the Dallas Morning News, Modern Health Care, Managed Healthcare, Health Leaders, and a many other national and local publications. You can get more information about her health industry experience **here**. If you need assistance responding to concerns about the matters discussed in this publication or other health care concerns, wish to obtain information about arranging for training or presentations by Ms. Stamer, wish to suggest a topic for a future program or update, or wish to request other information or materials, please contact Ms. Stamer via telephone at (214) 452-8297 or via e-mail **here**.

If you or someone else you know would like to receive future updates about developments on these and other concerns from Ms. Stamer, see **here**. If you find this of interest, you also be interested reviewing some of her other writings including:

- **Minimum Wage, Overtime Risks Highlighted By Labor Department Strike Force Targeting Residential Care & Group Homes**
- **Health Care Fraud Enforcement Packs New Heat**
- **President Signs Long-Sought Red Flag Rule Exemption Into Law**
- **Quality, Recordkeeping & Unprofessional Conduct Lead Reasons For Medical Board Discipline of Physicians**
- **CMS Finalizes Calendar Year 2011 Physician Fee Schedule & Other Medicare Part B Payment Policies**
- **DEA Cautions Practitioners Must Restrict Delegation of Controlled Substance Prescribing Functions, Urges Adoption of Written Policies & Agreements**

- **Avoiding Post-Holiday Celebration Sexual Harassment & Discrimination Liability**
- **Small Employers Should Weigh If Health Premium Tax Credit Justifies Changing Employee Leasing Arrangements**
- **2011 Standard Mileage Rates Announced**
- **Update Employment Practices To Manage Genetic Info Discrimination Risks Under New EEOC Final GINA Regulations**
- **EEOC Attacks Medical Leave Denials As Prohibited Disability Discrimination**
- **New Insured Group Health Plan Non-Discrimination Rules Create Significant Liability For Employers & Insurers; Prompt IRS Also To Review Self-Insured Group Health Plan Rules**
- **Affordable Care Act's Health Plan External & Internal Review Safe Harbor & Other Regulations Require Health Plan Updates**
- **New Rule Requires Federal Government Contractors To Post New "Employee Rights Under The National Labor" Poster**
- **Employers Concerned About New Union Powers As NLRB Orders Union Elections In 31 California Health Care Facilities To Proceed**
- **CMS Delegated Lead Responsibility For Development of New Affordable Care Act-Required Medicare Self-Referral Disclosure Protocol**
- **HHS announces Rules Implementing Tools Added By Affordable Care Act to Prevent Federal Health Program Fraud**
- **OIG: Texas Overbilled Medicaid for Medical Transportation Costs**
- **DMEPOS Suppliers Face 9/27 Deadline To Meet Tightened Medicare Standards**
- **HHS Announces Adjustments to Federal Medical Assistance Percentage (FMAP) Rates**
- **CMS Publishes Corrections To Proposed 2011 Physician Fee Schedule Rules**
- **Medicare Changing How It Pays For Outpatient Dialysis**
- **Rite Aid Agrees to Pay $1 Million to Settle HIPAA Privacy Case As OCR Moves To Tighten Privacy Rules**
- **CMS Adopts ESRD Facility Prospective Payment System & Proposes New Quality Incentive Program**
- **CMS Rule Clarifies When Outpatient Services Subject to 3-Day Rule & Finalizes FY 2011 Inpatient Payment Rates**
- **New Affordable Care Act Mandated High Risk Pre-Existing Condition Insurance Pool Program Regulations Set Program Rules, Prohibit Plan Dumping of High Risk Members**