



DEPARTMENT OF HEALTH AND HUMAN SERVICES
OFFICE OF INSPECTOR GENERAL

WASHINGTON, DC 20201



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TO: Marilyn Tavenner
Administrator
Centers for Medicare & Medicaid Services

/s/

FROM: Brian P. Ritchie
Acting Deputy Inspector General
for Evaluation and Inspections

SUBJECT: Information on the Annual Fee on Branded Prescription Drug Companies Under the Affordable Care Act

This memorandum provides information about funds received by the Federal Supplementary Medical Insurance (Medicare Part B) Trust Fund (hereinafter referred to as the Trust Fund) through the annual fee on branded prescription drug companies, pursuant to section 9008 of the Affordable Care Act (ACA), P.L. 111-148. Section 9008, as amended, directs branded prescription drug companies to pay to the Secretary of the Treasury fees totaling \$2.5 billion in 2011, \$2.8 billion in 2012, and \$2.8 billion in 2013. Companies are required to pay their fees to the Department of the Treasury (Treasury) each year by September 30. An amount equal to the fees received by Treasury each year is to be transferred to the Trust Fund. The total annual fee amount to be paid will rise to \$4.1 billion in 2018, then will return to \$2.8 billion in 2019 and remain at that level thereafter. The Office of Inspector General (OIG) reviewed the fee amounts received by the Trust Fund for the 2011 and 2012 fee years. I am providing this information for your review and consideration with respect to the Centers for Medicare & Medicaid Services' (CMS) monitoring- and accounting-related roles in relation to the Trust Fund.

We found that the Trust Fund received \$2.5 billion for the 2011 fee, which equals the full amount that was to be paid by the companies for 2011. Of this amount, \$1.876 billion was received by the Trust Fund in September 2011 and \$624 million was received in December 2011. For the 2012 fee, the Trust Fund received all but \$245,000 of the \$2.8 billion amount that the ACA provides for the 2012 fee. The Trust Fund received \$2.184 billion in September 2012, \$603 million in April 2013, and \$13 million in May 2013.

According to CMS, after we sent our data request for the 2011 and 2012 fee years, the Trust Fund received approximately \$2.6 billion in October 2013 and \$199 million in December 2013, which is all but \$693,000 of the \$2.8 billion amount that the ACA provides for the 2013 fee.

This means that between September 2011 and December 2013, the Trust Fund received all but \$938,000 of the total \$8.1 billion amount the ACA provides for the first 3 fee years. However, to the extent that the fees were not in the Trust Fund, the Trust Fund may have missed an opportunity to earn interest income on these fees. For the 2011 and 2012 fees, CMS used data that it received from Treasury to report on the fee's activity and make actuarial projections.

BACKGROUND

Annual Fee on Branded Prescription Drug Companies

Under the ACA, manufacturers and importers of branded prescription drugs (hereinafter referred to as companies) are required to pay a collective annual fee, totaling \$2.5 billion in 2011, \$2.8 billion in 2012, and \$2.8 billion in 2013.¹ This annual fee will rise to \$4.1 billion in 2018, then return to \$2.8 billion in 2019 and remain at that level thereafter.

Generally, any company with over \$5 million in annual branded prescription drug sales made to or covered by specified Government programs pays a share of the fee relative to its share of all such sales.² The specified Government programs are defined as including Medicare Part B; Medicare Part D; Medicaid; any program under which branded prescription drugs are procured by the Department of Veterans Affairs or the Department of Defense; and the TRICARE retail pharmacy program.³ Companies are required to pay their fees to Treasury by September 30 each fee year,⁴ which is defined as the calendar year in which the fee must be paid (e.g., payments for the 2011 fee year were due no later than September 30, 2011).⁵

In accordance with the ACA, Treasury administers the fee process.⁶ The ACA appropriates to the Trust Fund an amount equal to the fees received by Treasury from the companies.⁷ The ACA does not specify a timeframe for transferring the fees to the Trust Fund. Certain factors may affect Treasury's collection of the fee and subsequent transfer of it to the Trust Fund, such as disputes over the allocated amount and difficulties collecting payment from certain manufacturers. The Trust Fund is managed for CMS by the Bureau of the Public Debt (BPD) at Treasury,⁸ and the assets of the Trust Fund are held in Treasury securities, which earn interest income.

¹ Section 9008 of the ACA, as amended by section 1404 of the Health Care and Education Reconciliation Act of 2010 (P.L. 111-152).

² Sections 9008(a), (b), and (e) of the ACA. For purposes of this fee, a branded prescription drug is defined as "any prescription drug the application for which was submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(b))" or "any biological product the license for which was submitted under section 351(a) of the Public Health Service Act (42 U.S.C. 262(a))." Section 9008(e)(2)(A) of the ACA; 26 CFR § 51.2T(c).

³ Section 9008(e)(4) of the ACA.

⁴ 26 CFR § 51.8T(c). The ACA and 26 CFR pt. 51 do not provide a deadline for the transfer of the fees to the Trust Fund.

⁵ 26 CFR § 51.2T(g).

⁶ Section 9008 of the ACA, and 26 CFR pt. 51T.

⁷ Section 9008(c) of the ACA.

⁸ Section 1841(b) of the Social Security Act. Also see BPD, *Government Agency Investment Services*. Accessed at <http://www.publicdebt.treas.gov/whatwedo/government.htm> on February 15, 2013.

CMS’s Responsibilities With Respect to the Part B Trust Fund

Two CMS components that are involved in the operations of the Trust Fund are the Office of Financial Management (OFM) and the Office of the Actuary (OACT). OFM reconciles all CMS financial data and prepares external reports; formulates, presents, and executes all CMS budget accounts; performs cash management activities; and prepares financial statements. OACT evaluates operations of the Trust Fund; publishes cost projections and economic analyses; conducts and directs the actuarial program for CMS; and provides program estimates for use in the President’s budget and for reports required by Congress.

RESULTS

The Trust Fund received the \$2.5 billion amount provided for by the ACA for 2011, and all but \$245,000 of the \$2.8 billion amount in 2012

Using data that we collected from CMS and from Treasury’s Web site, we found that the Trust Fund received \$2.5 billion for the 2011 fee, an amount equal to the amount to be paid by the companies for 2011 under the ACA.⁹ Through September 2011, the Trust Fund had received \$1.876 billion. In December 2011, the Trust Fund received the remaining \$624 million. See Table 1 for more data on the 2011 fee.

Table 1: Part B Trust Fund Account Data, 2011 Fee

Month	Activity
September 2011	\$1,875,727,329.16
October 2011	\$0.00
November 2011	\$0.00
December 2011	\$624,272,670.84
Total Activity, 2011 Fee¹	\$2,500,000,000.00
Amount Provided for by the ACA, 2011 Fee	\$2,500,000,000.00

Source: Treasury Web site (Trust Fund account number TFM5800630) and CMS data.

¹ The financial statements also reported \$0 in activity for this fee from January 2012 through August 2012.

For the 2012 fee, we found that the Trust Fund received all but \$245,000 of the \$2.8 billion amount provided for by the ACA.¹⁰ In September 2012, the Trust Fund received \$2.184 billion. No additional activity was reported in the Trust Fund for this fee through March 2013. After OIG notified CMS in March 2013 that the Trust Fund had not received the full \$2.8 billion for the 2012 fee, CMS contacted Treasury to determine the fee’s collection status. The Trust Fund subsequently received an additional \$603 million in April 2013 and \$13 million in May 2013. (No funds were received from June through August 2013.) As shown in the detailed breakdown in Table 2, the Trust Fund received all but \$245,000 of the \$2.8 billion amount that the ACA provides for the 2012 fee.

⁹ Our analysis was based on data from CMS and Treasury’s Web site on funds transferred to the Trust Fund. We did not follow up with Treasury to verify the accuracy of the data from CMS or Treasury’s Web site, nor did we determine whether funds had been received by the Internal Revenue Service but not transferred to the Trust Fund.

¹⁰ These data reflect Trust Fund data through August 2013.

Table 2: Part B Trust Fund Account Data, 2012 Fee

Month	Activity
September 2012	\$2,183,532,192.00
October 2012	\$0.00
November 2012	\$0.00
December 2012	Not listed ¹
January 2013	Not listed ¹
February 2013	Not listed ¹
March 2013	\$0.00
April 2013	\$603,009,449.30
May 2013	\$13,213,828.36
June 2013	\$0.00
July 2013	\$0.00
August 2013	\$0.00
Total Activity, 2012 Fee²	\$2,799,755,469.66
Amount Provided for by the ACA, 2012 Fee	\$2,800,000,000.00

Source: Treasury Web site (Trust Fund account number TFM5800630 through November 2012, TFMA58006300 from March through August 2013) and CMS data.

¹ In these months, the Trust Fund financial statements did not list the account for this fee.

² Through the August 2013 Trust Fund financial statement.

Furthermore, after we sent our data request to CMS for the 2011 and 2012 fee years, CMS reported that the Trust Fund received approximately \$2.6 billion in October 2013 and \$199 million in December 2013,¹¹ which is all but \$693,000 of the \$2.8 billion amount that the ACA provides for the 2013 fee. This means that, through December 2013, the Trust Fund received all but \$938,000 of the total \$8.1 billion amount the ACA provides for the first 3 fee years.

For the 2011 and 2012 fee years, CMS’s policies and procedures regarding the fee were primarily limited to reporting the fee in its annual financial reports and projecting estimated Trust Fund balances for actuarial use

Using information on CMS’s policies and procedures from its responses to interviews and questionnaires, we found that OFM received data from BPD regarding the Trust Fund account for the fee. For the 2011 and 2012 fee years, OFM used these data to report on income for the

¹¹ These data reflect Trust Fund data through December 17, 2013.

fee in CMS’s 2011 and 2012 financial reports.^{12, 13} OFM reported that—because BPD is the manager of the Trust Fund—it was not aware of the total fee amount provided for under the ACA, and it did not actively monitor the fee in the Trust Fund to ensure this amount was received each year. OFM stated that it “fully believes this is [a Treasury] and BPD function.”

OACT reported that it is responsible for projecting the operations of the Trust Fund and that the fees based on section 9008 of the ACA are included in the projected operations. OACT reported that it uses data reported by BPD primarily to project estimated Trust Fund balances for actuarial use. These reports include data on the activity of the branded drug fee. OACT stated that it has no specific procedures regarding this fee, and that it handles data on the fee in the same manner as all other data it receives from BPD.

When the Trust Fund financial statements reported on Treasury’s Web site did not list the account for this fee after November 2012, OACT followed up with Treasury to bring the matter to Treasury’s attention. The account for this fee was then listed again in the March 2013 Trust Fund financial statement. Treasury stated that these glitches in the reporting process between Treasury and CMS should be avoidable for the 2013 fee.

CONCLUSION

Although the funds from the annual fee are allocated to the Part B Trust Fund, the ACA grants to Treasury the responsibility of administering the fee process, including transferring the fee to the Trust Fund. To the extent that the fees were not in the Trust Fund, the Trust Fund may have missed an opportunity to earn interest income on these fees. Our results indicate that it may be beneficial for CMS to periodically monitor the status of this fee in the Trust Fund, and to contact Treasury if CMS finds that the full amount to be collected under the ACA each year has not been received.

If you have comments or questions about this information, please contact me, or your staff may contact Robert A. Vito, Regional Inspector General for Evaluation and Inspections, at (215) 861-4558 or through email at Robert.Vito@oig.hhs.gov.

¹² CMS’s financial reports are produced annually and include financial statements that report Trust Fund activity on a fiscal-year basis. CMS, *CMS Financial Report, Fiscal Year 2011*. Accessed at http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/CFORReport/downloads/2011_CMS_Financial_Report.pdf on March 26, 2013.

¹³ OFM stated that it reported activity under this fee in CMS’s annual financial report as part of the “Other Nonexchange Revenue” under the Supplementary Medical Insurance column in the Statement of Changes in Net Position.