

Department of Health and Human Services

**OFFICE OF
INSPECTOR GENERAL**

**MEDICARE PART D
E-PRESCRIBING STANDARDS:
EARLY ASSESSMENT SHOWS
PARTIAL CONNECTIVITY**



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E X E C U T I V E S U M M A R Y

OBJECTIVE

To determine the extent of Medicare Part D plan sponsors' implementation of electronic prescribing (e-prescribing) standards to support connectivity with prescribers and dispensers.

BACKGROUND

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 established the Medicare Part D e-prescribing program, which stipulates that plan sponsors must implement e-prescribing standards specified by the Secretary of the Department of Health and Human Services (the Secretary). E-prescribing standards facilitate the communication of prescription information among prescribers (e.g., physicians), Part D plan sponsors, and dispensers (e.g., pharmacies).

On behalf of the Secretary, the Centers for Medicare & Medicaid Services (CMS) established e-prescribing standards. Three of these standards enable the flow of eligibility, medication history, and formulary and benefits information between plan sponsors and prescribers at the point of care. These plan-to-prescriber standards are Accredited Standards Committee X12N 270/271, SCRIPT 8.1, and Formulary & Benefits Standard 1.0. Further, Formulary & Benefits Standard 1.0 consists of four components: Formulary Status List, Formulary Alternatives List, Coverage List, and Copayment List. The flow of eligibility information and copayment amounts between plan sponsors and dispensers is supported by one standard, Telecommunication 5.1. CMS required that plan sponsors implement two standards by January 2006 and the remaining standard by April 2009. In some cases, however, plan sponsors are exempt from implementing SCRIPT 8.1.

Between August and September 2008, we surveyed all Part D plan sponsors for plan year 2008 to determine the extent of their implementation of the standards. We received responses from 262 plan sponsors for a 94-percent response rate.

FINDINGS

Nearly 80 percent of plan sponsors reported at least partial plan-to-prescriber connectivity but few reported complete connectivity. Seventy-seven percent of plan sponsors responding to our survey reported either partial or complete implementation of the

plan-to-prescriber standards. Sixty-nine percent of plan sponsors reported partial plan-to-prescriber connectivity. In contrast, only 8 percent of plan sponsors reported complete connectivity. Additionally, 16 percent of plan sponsors reported no plans to achieve plan-to-prescriber connectivity. The remaining plan sponsors did not provide information on plan-to-prescriber connectivity.

Problems implementing Formulary & Benefits Standard 1.0 limit complete plan-to-prescriber connectivity.

Plan sponsors’ plan-to-prescriber connectivity is limited because only 8 percent of plan sponsors have completely implemented Formulary & Benefits Standard 1.0. In contrast, over 70 percent of plan sponsors reported complete implementation of each of the other two plan-to-prescriber standards. To achieve complete plan-to-prescriber connectivity, plan sponsors have to completely implement all three plan-to-prescriber standards.

Of the Formulary & Benefits Standard 1.0 components, fewer plan sponsors reported complete implementation of the Coverage List and the Copayment List than the Formulary Status List and the Formulary Alternatives List. According to plan sponsors, the batch data upload process (a way of transmitting data at specified intervals) is a barrier to complete implementation of the Coverage List and the Copayment List.

Only 5 percent of plan sponsors reported no plan-to-dispenser connectivity.

Five percent of plan sponsors responding to our survey reported no plans to implement the plan-to-dispenser standard. These plan sponsors are Program for All-Inclusive Care for the Elderly (PACE) plan sponsors. Most of these PACE plans reported that they believed that they were exempt from e-prescribing requirements. Entities that only send prescriptions internally are exempt from implementing SCRIPT 8.1, but no exemption exists for the plan-to-dispenser standard, Telecommunication 5.1.

Eighty-three percent of plan sponsors reported complete plan-to-dispenser connectivity. The remaining plan sponsors did not provide information on plan-to-prescriber connectivity.

RECOMMENDATIONS

Based on the results of our review, CMS should:

Ensure that plan sponsors completely implement the plan-to-prescriber and plan-to-dispenser standards. To achieve this, CMS could: (1) continue to educate plan sponsors about e-prescribing

requirements; (2) clarify e-prescribing standards exemptions; or (3) use available compliance mechanisms when necessary, such as corrective action plans and civil monetary penalties, to bring plan sponsors into compliance.

Collaborate with plan sponsors and industry representatives to address barriers to full implementation of Formulary & Benefits

Standard 1.0. CMS should collaborate with plan sponsors, pharmaceutical benefits managers, and standards-development organizations to address the batch-processing problems identified in this report. CMS could consider pilot-testing a real-time standard that enables plan sponsors to transmit beneficiary-specific formulary and benefits information.

AGENCY COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

CMS concurred with each of our recommendations. To address our recommendations, CMS will continue to educate plan sponsors about e-prescribing requirements. If necessary, CMS will also use available compliance mechanisms to bring plan sponsors into compliance. In addition, CMS plans to continue its collaboration with the National Council for Prescription Drug Programs, Inc., to continually update and develop new e-prescribing standards.

Although CMS concurred with our recommendations, it asserted there were significant methodological limitations with our data collection and analysis, resulting in inflated findings of plan sponsor noncompliance with e-prescribing standards. Specifically, CMS asserted that our results would have likely been different if our plan sponsor survey had been conducted closer to the implementation deadline. If we had conducted our survey at a later date, we acknowledge that implementation rates could have risen. However, we do not believe that the results reported here are inflated. CMS did conduct educational activities that clarified requirements; however, plan sponsors reported that technical difficulties were often a barrier to complete implementation, rather than a lack of clarity regarding the regulations.



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OBJECTIVE

To determine the extent of Medicare Part D plan sponsors' implementation of electronic prescribing (e-prescribing) standards to support connectivity with prescribers and dispensers.

BACKGROUND

In general, e-prescribing is the electronic communication of prescription information among health insurance companies, doctors, and pharmacies. E-prescribing is one example of health information technology, which the Presidential agenda outlines as a way to improve care and lower health care costs.¹ E-prescribing benefits that may lower costs include decreased adverse drug events, increased clinical efficiency, and increased generic utilization. A 2008 study indicated that, with access to formulary information, doctors prescribed lower cost medications, leading to an estimated savings of \$845,000 per 100,000 patients.²

E-prescribing benefits result from prescriber access to prescription information at the point of care. To make prescription information available at the point of care, e-prescribing systems use uniform standards that enable multiple data systems to exchange information with one another. Without e-prescribing standards, different data systems cannot send and receive drug information, limiting benefits such as improved patient safety, increased clinical efficiency, and cost savings.

Traditional Prescribing Versus E-Prescribing

Traditional prescribing occurs when a prescriber provides a written prescription to a beneficiary. Prescribers are persons licensed to issue prescriptions for drugs (e.g., physicians, dentists, or physician assistants).³ Then, a beneficiary takes the prescription to a dispenser to be filled. Dispensers are persons or other legal entities licensed to dispense prescription drugs (e.g., pharmacies).⁴ A dispenser may call a

¹ The White House, "The Agenda: Technology." Available online at <http://www.whitehouse.gov/agenda/technology/>. Accessed on March 13, 2009.

² M. Fischer, et al. (2008). "Effect of Electronic Prescribing with Formulary Decision Support on Medication Use and Cost." *Archives of Internal Medicine*, 168 (22), pp. 2433–2439.

³ 42 CFR § 423.159(a).

⁴ *Ibid.*

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prescriber to verify a drug dosage or to ask for authorization to dispense a generic drug. This followup may take several attempts if the prescriber is not available when the dispenser calls.

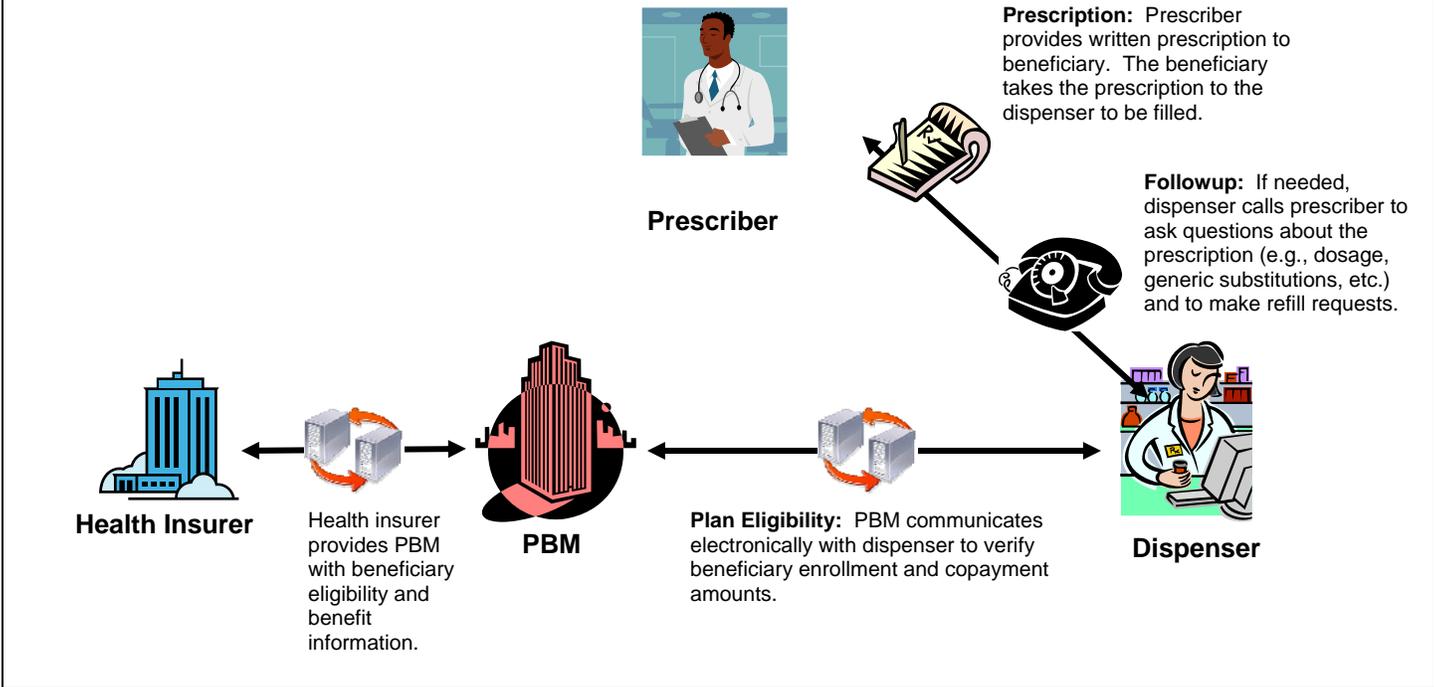
In contrast to traditional prescribing, e-prescribing occurs when a prescriber uses a computer or an electronic hand-held device, such as a personal digital assistant, to write and send a prescription directly to a dispenser. Before a prescriber sends a prescription to a dispenser, he or she can request beneficiary eligibility, formulary and benefits, and medication history information from a plan sponsor or its pharmaceutical benefits manager (PBM). PBMs are companies that provide pharmacy support services to plan sponsors, including claims processing and adjudication.

Prescribers can use prescription information to prescribe low-cost, alternative drugs and potentially avoid adverse drug events, such as drug allergies or drug-to-drug interactions. Plan-to-prescriber communication is a new feature in the prescribing process that is not available in traditional prescribing.

Plan-to-dispenser communication in e-prescribing works the same as in traditional prescribing. Dispensers electronically communicate with health insurers or with the insurers' PBMs to obtain beneficiary eligibility information and copayment amounts. PBMs communicate prescription information to dispensers on behalf of the health insurers with which they contract.

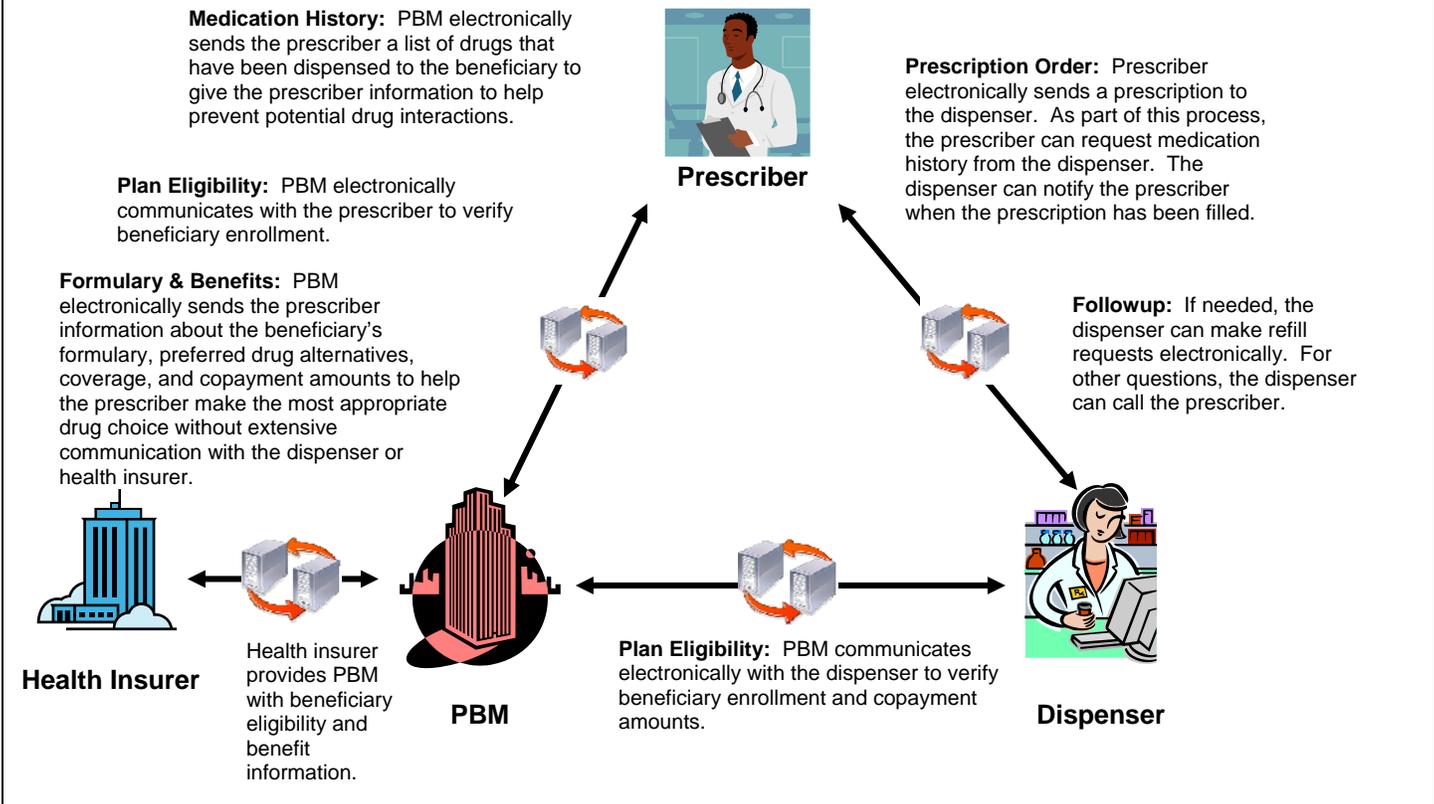
Figures 1 and 2 illustrate the communication among health insurers, PBMs, prescribers, and dispensers in traditional prescribing and e-prescribing.

Figure 1. Flow of Prescription-Related Information in Traditional Prescribing



Source: Office of Inspector General (OIG) analysis, 2008.

Figure 2. Flow of Prescription-Related Information in E-Prescribing



Source: OIG analysis, 2008.

Medicare Prescription Drug, Improvement, and Modernization Act of 2003

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) established the Medicare prescription drug program, known as Medicare Part D, which provides optional drug benefits to Medicare beneficiaries.⁵ The Centers for Medicare & Medicaid Services (CMS) contracts with private insurance companies, known as plan sponsors, to provide prescription drug coverage for beneficiaries who choose to enroll in the program. Plan sponsors may offer prescription coverage as a stand-alone prescription drug plan or as part of a managed care plan, known as a Medicare Advantage Prescription Drug Plan.⁶ As of February 2009, approximately 26.6 million beneficiaries were enrolled in Medicare Part D.⁷

MMA and E-Prescribing

The MMA also established the Medicare Part D e-prescribing program,⁸ which requires that plan sponsors support e-prescribing activities by implementing e-prescribing standards specified by the Secretary of the Department of Health and Human Services (the Secretary).⁹

E-prescribing standards enable interoperability among e-prescribing systems. With interoperable systems, plan sponsors, prescribers, and dispensers can exchange drug information with one another. The Secretary delegated oversight of plan-sponsor implementation of the e-prescribing standards to CMS.

The requirement to implement e-prescribing standards is incorporated into plan sponsors' contracts.¹⁰ CMS contracts with plan sponsors by

⁵ Title I of the MMA, P.L. No. 108-173, Part D of Title XVIII of the Social Security Act, 42 U.S.C. § 1395w-101 et seq.

⁶ MMA, P.L. No. 108-173 § 101(a), Social Security Act, § 1860D-1(a)(1), 42 U.S.C. § 1395w-101(a)(1).

⁷ CMS, "Total Medicare Beneficiaries With Prescription Drug Coverage." 2009. Available online at <http://www.cms.hhs.gov/PrescriptionDrugCovGenIn/>. Accessed on February 23, 2009.

⁸ MMA, P.L. No. 108-173 § 101(a), Social Security Act, § 1860D-4(e), 42 U.S.C. § 1395w-104(e).

⁹ 42 CFR § 423.160(a). Although the MMA does not explicitly mandate that plan sponsors support e-prescribing, CMS has interpreted the e-prescribing program established at section 1860D(4) of the Social Security Act as being unworkable without such mandatory support. See 69 Fed. Reg. 46632, 46671 (Aug. 3, 2004).

¹⁰ 42 CFR § 423.505(b)(6).

September for the following plan year, which begins in January.¹¹ Because CMS includes e-prescribing requirements in plan sponsor contracts, it may institute corrective action plans, issue civil monetary penalties, and terminate plan sponsors' contracts for plan sponsors that fail to implement the e-prescribing standards.¹²

E-Prescribing Standards

CMS established four e-prescribing standards to support the interoperability of plan sponsors' e-prescribing systems with other e-prescribing systems. CMS required that plan sponsors implement two standards by January 2006.¹³ In April 2008, CMS issued a final rule requiring that plan sponsors implement two additional standards by April 2009.¹⁴ Table 1 describes the e-prescribing standards and groups them according to whether they facilitate plan-to-prescriber or plan-to-dispenser connectivity.

Table 1: E-Prescribing Standards for Medicare Part D Plan Sponsors			
Connectivity	E-Prescribing Standard	Implementation Deadline	Flow of Prescription Information
Plan-to-Prescriber Connectivity	Accredited Standards Committee (ASC) X12N 270/271	January 2006	Plan sponsors respond to prescribers' requests about beneficiary eligibility.
	SCRIPT 8.1	April 2009	Plan sponsors respond to prescribers' requests for a beneficiary's Part D medication history.
	Formulary & Benefits Standard 1.0	April 2009	Plan sponsors respond to prescribers' requests for formulary, alternative drug, coverage, and copayment information.
Plan-to-Dispenser Connectivity	Telecommunication 5.1	January 2006	Plan sponsors respond to dispensers' requests about eligibility and copayment amounts.

Source: OIG analysis of e-prescribing standards, 2008.

CMS provided education to plan sponsors about e-prescribing requirements. In September 2008, CMS issued a memorandum reminding plan sponsors of the implementation deadlines for each standard and reiterating the expectation that all components of each

¹¹ CMS, "Solicitation for Applications for New Prescription Drug Plans Sponsors: 2010 Contract Year," 2009. Available online at <http://www.cms.hhs.gov/PrescriptionDrugCovContra/Downloads/PDPAApplication.pdf>. Accessed on June 12, 2009.

¹² 42 CFR §§ 423.509(a)(1) and (c) and 42 CFR § 423.752(c)(1).

¹³ 42 CFR §§ 423.160(b)(2)(i) and (ii), as promulgated in 70 Fed. Reg. 67568, 67573 (Nov. 7, 2005), now found at 42 CFR §§ 423.160(b)(3)(i) and (ii). CMS also established a standard for transmitting prescriptions at what is now 42 CFR § 423.160(b)(2), effective January 2006. However, we did not test this standard as it is the only standard in use for the transmission of electronic prescriptions.

¹⁴ 42 CFR §§ 423.160(b)(1), (b)(4), and (b)(5), as promulgated in 73 Fed. Reg. 18918, 18926 (Apr. 7, 2008).

standard be implemented.¹⁵ Additionally, CMS held an e-prescribing conference in October 2008. The conference included educational sessions and presentations about e-prescribing, e-prescribing standards, and the effective date for standards implementation.

Plan-to-prescriber connectivity. CMS established three e-prescribing standards to be used by plan sponsors, or PBMs on their behalf, when communicating prescription information to prescribers. These are ASC X12N 270/271, SCRIPT 8.1, and Formulary & Benefits Standard 1.0.

ASC X12N 270/271 and SCRIPT 8.1 require that plan sponsors populate drug information through a real-time transaction. A real-time transaction is a process by which plan sponsors send current eligibility and medication history information for each beneficiary upon request.

Formulary & Benefits Standard 1.0 is composed of four components: Formulary Status List, Formulary Alternatives List, Coverage List, and Copayment List. Each component is further divided into several elements. See Appendix A for a detailed description of Formulary & Benefits Standard 1.0 components.

Formulary & Benefits Standard 1.0 requires that plan sponsors populate component information through a batch data upload process. A batch data upload is the process by which plan sponsors send batches of formulary and benefit information at specified intervals, such as weekly or monthly, rather than providing information for each beneficiary upon request. CMS adopted this process because of successful pilot-testing and because it was the current industry practice for sending Formulary Status List information.¹⁶

Plan-to-dispenser connectivity. CMS established one e-prescribing standard to be used when plan sponsors, or PBMs on their behalf, communicate prescription information to dispensers. This standard is Telecommunication 5.1. Plan sponsors use a real-time transaction for Telecommunication 5.1 to communicate beneficiary eligibility

¹⁵ CMS, Memorandum to Part D Sponsors, "Supporting Electronic Prescribing Under Medicare Part D," September 19, 2008.

¹⁶ 73 Fed. Reg. 18918, 18924 (Apr. 7, 2008).

information and copayment amounts to dispensers. CMS adopted this standard because it was already widely used in the pharmacy industry.¹⁷

E-Prescribing Standards Exemptions

In some cases, plan sponsors are exempt from implementing SCRIPT 8.1. Implementation of SCRIPT 8.1 is optional for entities¹⁸ that transmit prescriptions or prescription information internally.¹⁹ In these cases, sometimes referred to as “closed e-prescribing systems,” the prescriber and the recipient (e.g., a pharmacy) are part of the same legal entity. However, the entity is required to use SCRIPT 8.1 for any electronic prescriptions for a Part D beneficiary sent to an external recipient.²⁰ Entities that transmit prescriptions by computer-generated facsimile or are required by law to issue a written prescription for a patient to a nonprescribing provider, such as a nursing facility, are also exempt from using this standard.²¹

Related OIG Reports

In 2007, OIG conducted a study that evaluated State Medicaid agencies’ implementation of health information technology initiatives, which included e-prescribing initiatives. OIG found that in 2007 several State Medicaid agencies were developing networks to enable health care providers and payers to securely exchange clinical information, such as prescription history.²²

OIG plans to release a companion e-prescribing report to this report. The companion report will provide details about Part D plan sponsor initiatives to promote e-prescribing among prescribers.

METHODOLOGY

Scope

We assessed plan sponsor e-prescribing connectivity by reviewing plan sponsors’ implementation of, or plans to implement, the four

¹⁷ 70 Fed. Reg. 67568, 67574 (Nov. 7, 2005).

¹⁸ Entities include plan sponsors, prescribers, PBMs, and other organizations that transmit prescriptions or prescription-related information.

¹⁹ 42 CFR § 423.160(a)(3)(iii).

²⁰ 42 CFR § 423.160(a)(1).

²¹ 42 CFR §§ 423.160(a)(3)(i) and (iv).

²² OIG, “State Medicaid Agencies’ Initiatives on Health Information Technology and Health Information Exchange,” OEI-02-06-00270, August 2007.

e-prescribing standards. We did not evaluate prescriber or dispenser e-prescribing volume or use of the standards.

Data Collection

We used CMS's Health Plan Management System (HPMS) data from July 2008 to identify plan sponsors and their associated PBMs for plan year 2008.²³ The HPMS provides information about Part D plans.

We also used HPMS data to identify the number of beneficiaries enrolled with each plan sponsor in 2008. As of July 2008, 26.2 million beneficiaries were enrolled in Part D.

Survey. Between August and September 2008, we conducted an email survey of all plan sponsors or their PBMs for plan year 2008. Although CMS allows exemptions to the e-prescribing standards, we did not exclude any plan sponsors from our study because CMS had not granted any exemptions.

The survey consisted of questions about the extent to which plan sponsors had implemented or planned to implement Part D e-prescribing standards. Where applicable, we asked plan sponsors to explain why they had not implemented the standards.

We followed up with plan sponsors and PBMs if they reported that they did not currently support e-prescribing and did not indicate their future plans to implement the e-prescribing standards. Through this followup, we determined these plan sponsors' and PBMs' future plans to implement the e-prescribing standards. We also placed phone calls and sent emails to plan sponsors and PBMs to clarify survey responses, when necessary.

We surveyed 278 plan sponsors. We received responses from 262 plan sponsors for a 94-percent response rate. Two-hundred eleven responses were provided by 29 of 31 PBMs that we surveyed on behalf of plan sponsors. Responses were provided by 51 of 61 plan sponsors without PBMs.

We conducted a pretest of the survey. Where appropriate, we revised the survey based on feedback from this pretest.

²³ The plan year begins in January and ends in December.

Data Analysis

We conducted our analysis at the plan sponsor level because plan sponsors are responsible for implementing the regulations. We did not assess the implementation of e-prescribing standards by individual plans offered by plan sponsors.

For our analysis of plan sponsor implementation of e-prescribing standards, we grouped the standards by the e-prescribing connectivity they facilitated: plan-to-prescriber or plan-to-dispenser.

Plan-to-prescriber connectivity includes three e-prescribing standards: ASC X12N 270/271, SCRIPT 8.1, and Formulary & Benefits Standard 1.0. Plan-to-dispenser connectivity includes only one e-prescribing standard: Telecommunication 5.1.

We then categorized plan sponsors' responses based on implementation status. To analyze plan-to-prescriber connectivity, we used four categories: complete, partial, no connectivity, and missing information. Of the three plan-to-prescriber standards, only Formulary & Benefits Standard 1.0 can be partially implemented because it has four distinct components.

In our analysis of these categories, we combined plan sponsors that reported implementation with those that reported that they were planning implementation. For example, the number of plan sponsors that have complete plan-to-prescriber connectivity includes plan sponsors that have complete connectivity and plan sponsors with plans to achieve complete connectivity. We took this approach to give plan sponsors as much credit for their efforts as possible because this is an early implementation review and we collected data before the April 2009 implementation deadline for SCRIPT 8.1 and Formulary & Benefits Standard 1.0.

Because Formulary & Benefits Standard 1.0 has several components, we conducted additional analysis of plan sponsors' implementation of this standard. To analyze plan sponsor implementation of the four Formulary & Benefits Standard 1.0 components, we divided each of the four components into the same four implementation categories outlined in the previous paragraph.

To analyze plan-to-dispenser connectivity, we divided the plan-to-dispenser standard into three implementation categories: complete, no connectivity, and missing information. Plan sponsors having complete connectivity have implemented or have plans to

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completely implement this standard. We did not have a partial connectivity category because Telecommunication 5.1 cannot be partially implemented.

See Appendix B for a detailed description of the plan-to-prescriber, plan-to-dispenser, and Formulary & Benefits Standard 1.0 component analysis categories.

Limitations

This report relies on self-reported data. We did not validate plan sponsor or PBM responses.

Standards

This study was conducted in accordance with the “Quality Standards for Inspections” approved by the Council of Inspectors General on Integrity and Efficiency.

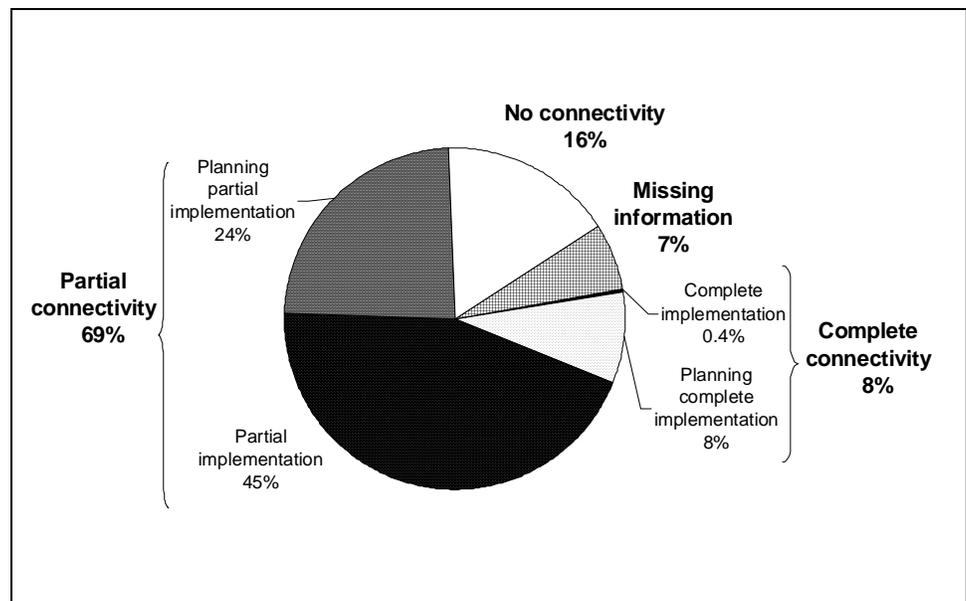
► FINDINGS

Nearly 80 percent of plan sponsors reported at least partial plan-to-prescriber connectivity but few reported complete connectivity

Seventy-seven percent of plan sponsors responding to our survey reported either partial or complete implementation of the

plan-to-prescriber standards. Sixty-nine percent of plan sponsors reported that they had partially implemented or planned to partially implement the plan-to-prescriber standards. In contrast, only 8 percent of plan sponsors (23 plan sponsors) reported that they had implemented or planned to implement all three plan-to-prescriber standards to achieve complete plan-to-prescriber connectivity. See Appendix C for plan sponsors' implementation of each standard. Chart 1 shows the status of plan sponsor plan-to-prescriber connectivity.

Chart 1. Plan Sponsors' Plan-to-Prescriber Connectivity



Source: OIG analysis of survey data, 2008.

While our assessment took place 7 months before the April 2009 deadline for two of the plan-to-prescriber standards, it is reasonable to expect that, at that time, all plan sponsors would have been aware of these standards and would have either implemented them or had plans to implement them.

Plan sponsors should have known of the final implementation deadline by April 2008. CMS required plan sponsors to implement one of the plan-to-prescriber standards by January 2006. Further, CMS issued the final rule for the other two standards in April 2008. Also, CMS

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issued a memorandum in September of 2008 reminding plan sponsors of the standards implementation requirements and deadlines. Further, fiscal year 2009 contracts with CMS required that plan sponsors support e-prescribing activities. As in other years, these contracts would have been in place by September.

In addition, for plan sponsors to achieve complete connectivity by the April 2009 deadline, implementation planning would have to begin earlier. Industry representatives have indicated that setup and implementation of e-prescribing standards takes 3 to 6 months on average.

Sixty-nine percent of plan sponsors reported partial plan-to-prescriber connectivity

Forty-five percent of plan sponsors reported that they had partially implemented the plan-to-prescriber standards, and 24 percent reported plans to partially implement the plan-to-prescriber standards. These plan sponsors did not report plans to achieve complete implementation. Partial implementation of these standards limits prescriber access to prescription information at the point of care, which may limit the potential benefits of e-prescribing. In 2008, 69 percent of Part D beneficiaries (18.1 million beneficiaries) were enrolled with plan sponsors that reported partial plan-to-prescriber connectivity.

Of the 24 percent of plan sponsors planning to partially implement the plan-to-prescriber standards, 34 percent planned to do so by April 2009. Sixteen percent reported plans to partially implement these standards after April 2009 but did not provide specific dates for implementation. Another 50 percent of plan sponsors did not specify whether they planned to implement these standards before or after April 2009.

Eight percent of plan sponsors reported complete plan-to-prescriber connectivity

Of the 8 percent of plan sponsors reporting complete plan-to-prescriber connectivity, one plan sponsor reported that it had completely implemented all three plan-to-prescriber standards. The remaining 22 plan sponsors reported plans to completely implement the plan-to-prescriber standards. Approximately 30 percent of Part D beneficiaries (7.8 million beneficiaries) were enrolled with these 23 plan sponsors in 2008. Approximately 90 percent reported that they would implement all three of the standards by the April 2009 deadline.

Sixteen percent of plan sponsors reported no plans to achieve plan-to-prescriber connectivity

Plan sponsors that do not implement any of the plan-to-prescriber standards limit potential e-prescribing benefits, such as savings from increased generic substitution and decreased adverse drug events. In 2008, approximately 200,821 beneficiaries, or less than 1 percent, of Part D beneficiaries were enrolled with these plan sponsors.

Seventy percent of these plan sponsors are Program of All-Inclusive Care for the Elderly plan sponsors that may be exempt from the standards.

Seventy percent of plan sponsors that reported no plans to implement any of the plan-to-prescriber standards were Program of All-Inclusive Care for the Elderly (PACE) plan sponsors.²⁴ Of these 30 PACE plan sponsors, 18 reported that they are exempt from implementing the plan-to-prescriber standards because they are PACE plan sponsors. Some of these PACE plan sponsors offered a more specific explanation. They stated that they are exempt because they are closed prescribing systems. They reported that their prescriptions for beneficiaries are prescribed and filled internally or through a contracted pharmacy.

A few PACE plan sponsors provided additional reasons for not implementing the plan-to-prescriber standards related to being a closed prescribing system. Four PACE plan sponsors do not plan to implement SCRIPT 8.1. They reported that as PACE employees in a closed prescribing system, PACE prescribers already have access to beneficiaries' medication history. One PACE plan sponsor expressed confusion about whether it is required to implement the e-prescribing standards. The plan sponsor asked for clarification from CMS about its responsibilities regarding the e-prescribing standards.

Although some of these plan sponsors may be exempt from implementing SCRIPT 8.1 under the closed system exemption, PACE plan sponsors are not explicitly exempt. In addition, they are not exempt from implementing the remaining plan-to-prescriber standards, as the exemption covers only SCRIPT 8.1. None of the PACE plan sponsors provided us with official documentation stating that they were exempt from implementing the e-prescribing standards.

²⁴ A PACE organization is a not-for-profit private or public entity that is engaged primarily in providing comprehensive medical and social services. PACE services use an interdisciplinary team approach in an adult day health center.

FINDINGS

A few PACE plan sponsors provided other reasons for not planning to implement the plan-to-prescriber standards. Five PACE plan sponsors stated that they do not need to implement Formulary & Benefits Standard 1.0 because they do not use formularies. One other PACE plan sponsor expressed concern about the financial burden that may be caused by implementing the standards.

An additional 28 percent of plan sponsors gave no reason for not planning to implement any of the plan-to-prescriber standards. Twelve plan sponsors gave no reason for not planning to implement any of the plan-to-prescriber standards. Three PBMs represent 10 of these plan sponsors. The other two plan sponsors do not work with a PBM.

Problems implementing Formulary & Benefits Standard 1.0 limit complete plan-to-prescriber connectivity

Because only 8 percent of plan sponsors reported that they had completely implemented or planned to completely implement

all four components of Formulary & Benefits Standard 1.0, complete plan-to-prescriber connectivity is also low. On the other hand, over 70 percent of plan sponsors reported complete implementation of each of the other two plan-to-prescriber standards. In particular, 76 percent reported complete implementation of ASC X12N 270/271 and 79 percent reported complete implementation of SCRIPT 8.1. Despite these high implementation rates, plan sponsors' overall plan-to-prescriber connectivity is low because plan sponsors have to completely implement all three plan-to-prescriber standards to achieve complete plan-to-prescriber connectivity. For more details on the implementation status of each plan-to-prescriber standard, see Table C1 in Appendix C.

Plan sponsors reported varying rates of complete implementation of the four components that make up Formulary & Benefits Standard 1.0: Formulary Status List, Formulary Alternatives List, Coverage List, and Copayment List. Complete implementation rates for each of the four components ranged from a high of 71 percent to a low of 24 percent. Only one plan sponsor reported complete implementation of all four components.

Fewer plan sponsors reported complete implementation of the Coverage List and the Copayment List than the Formulary Status List and the Formulary Alternatives List

Complete implementation rates were the lowest for the Coverage List and the Copayment List. Thirty percent and twenty-four percent of plan sponsors reported that they had completely implemented or planned to completely implement the Coverage List and the Copayment List, respectively. In contrast, 71 percent and 56 percent of plan sponsors reported that they had completely implemented or planned to completely implement the Formulary Status List and the Formulary Alternatives List, respectively. Table 2 provides the implementation status of each component of Formulary & Benefits Standard 1.0. For more details on the implementation status by component, see Table C2 in Appendix C.

Table 2: Plan Sponsors’ Implementation of Formulary & Benefits Standard 1.0 Components

Component	Complete Implementation	Partial Implementation	Not Planning Implementation	Missing Information
Formulary Status List (n = 262)	71%	7%	2%	20%
Formulary Alternatives List (n = 262)	56%	0%	24%	20%
Coverage List* (n = 262)	30%	37%	13%	21%
Copayment List * (n = 262)	24%	14%	44%	20%

* Totals add to greater than 100 percent because of rounding.

Source: OIG analysis of survey data, 2008.

Plan sponsors offered reasons for not completely implementing the Formulary Alternatives List, Coverage List, and Copayment List.²⁵ In some cases, the reasons were specific to the component. For example, some plan sponsors not planning to implement the Formulary Alternatives List stated that this component duplicates information in the Formulary Status List. Others reported that determining alternative drug information was a clinical decision they did not feel they were in a position to make. For the Coverage List and the Copayment List, plan sponsors reported difficulties transmitting

²⁵ Plan sponsors did not offer any reasons for not completely implementing the Formulary Status List.

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complete data, which prevents complete implementation of these components.

The batch data upload process is a barrier to complete implementation of the Coverage List and the Copayment List

According to 80 percent of plan sponsors that lacked complete plan-to-prescriber connectivity, the batch data upload process is a barrier to complete implementation of the Coverage List and the Copayment List components of Formulary & Benefits Standard 1.0. Eleven PBMs represent these plan sponsors.

Plan sponsors explained that their current processing systems are not compatible with the batch process. Their processing systems are built to handle real-time transactions for claims processing. Plan sponsors reported that they would have to make custom changes to their systems to make them compatible with batch processing. Some plan sponsors' PBMs have taken this step but reported that it is expensive and does not enable plan sponsors to transmit comprehensive beneficiary-level data for coverage and copayment information.

According to industry comments in CMS's final e-prescribing rule, using the batch process instead of a real-time process results in beneficiary information that is often outdated and lacks detail.²⁶ This can lead to higher copayments for patients.²⁷ Thus, it prevents plan sponsors, PBMs, prescribers, and beneficiaries from fully realizing the benefits of e-prescribing. Figure 3 explains limitations of the batch data upload process.

²⁶ 73 Fed. Reg. 18918, 18924 (Apr. 7, 2008).

²⁷ Ibid.

Figure 3: Explanation and Examples of Problems With the Batch Data Upload Process in Formulary & Benefits Standard 1.0

Coverage and copay data are inadequately represented in a batch format as the batch data are provided only once a month and are often out of date. Additionally, batch data do not provide the patient level of information required to display the patient’s coverage and copay information. For example:

- If a medication requires a coverage review but that review was already completed and the medication approved for a specific member, there is no way to display the patient’s status in a batch framework.
- Most batch copay displays provide a simple reference point (for example, symbols that represent copay amounts ranging from low to high: \$, \$\$, \$\$\$), not the actual copay amount; this level of information is not as useful to a prescriber or patient as knowing the actual expense for the patient.

Source: OIG analysis of survey data, 2008.

CMS has also recognized the importance of a real-time formulary and benefits standard. In the April 2008 final rule, CMS indicated that a real-time standard for formulary and benefits information would be an important step towards realizing the potential benefit of the standard.²⁸ CMS also stated that once the current Formulary & Benefits Standard 1.0 is widely used, it expects marketplace forces to encourage incorporation of a real-time standard for formulary and benefits information.²⁹

Only 5 percent of plan sponsors reported no plan-to-dispenser connectivity

Five percent of plan sponsors (12 plan sponsors) responding to our survey reported no plans to implement the plan-to-dispenser

standard, which had an implementation date of January 2006. In 2008, less than 1 percent of Part D beneficiaries (17,375 beneficiaries) were enrolled with these plan sponsors. All 12 plan sponsors are PACE plan sponsors that also reported no plans to implement the plan-to-prescriber standards. Ten of the twelve plan sponsors reported that they did not implement the plan-to-dispenser standard because, as closed prescribing systems, they believed they were exempt from e-prescribing requirements. Entities that only send prescriptions within their organization are exempt from implementing SCRIPT 8.1, but no exemption exists for the plan-to-dispenser standard,

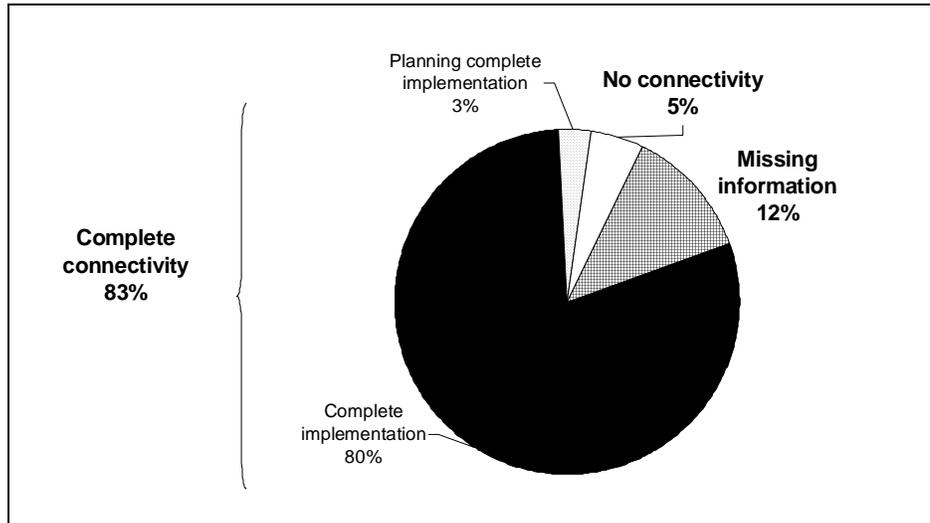
²⁸ 73 Fed. Reg. 18918, 18924 (Apr. 7, 2008).

²⁹ Ibid.

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Telecommunication 5.1. None of these PACE plan sponsors requested an exemption from CMS. Chart 2 shows the status of plan sponsor plan-to-dispenser connectivity.

Chart 2. Plan Sponsors' Plan-to-Dispenser Connectivity



Source: OIG analysis of survey data, 2008.

Eighty-three percent of plan sponsors reported that they had implemented or planned to implement Telecommunication 5.1. Eighty percent of plan sponsors reported that they had implemented the standard and an additional 3 percent of plan sponsors reported planning to implement the standard. In 2008, 78 percent of Part D beneficiaries (20.4 million beneficiaries) were enrolled with these plan sponsors.

An additional 12 percent of plan sponsors did not provide any information about implementation of the plan-to-dispenser standard. Twenty of these plan sponsors are PACE plan sponsors, one PBM represents five plan sponsors, and seven plan sponsors have no PBMs.



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As of September 2008, most plan sponsors had at least partial plan-to-prescriber connectivity but few reported complete connectivity. Plan-to-prescriber connectivity is limited because of problems with batch processing that prevent plan sponsors from completely implementing Formulary & Benefits Standard 1.0.

Partial plan-to-prescriber connectivity limits the potential benefits of e-prescribing because most e-prescribing benefits rely on prescriber access to prescription information at the point of care. These benefits include decreased adverse drug events, increased clinical efficiency, and increased generic utilization resulting in savings. A 2008 study indicated that, with access to formulary information, prescribers prescribed lower cost medications, leading to an estimated savings of \$845,000 per 100,000 patients.

On the other hand, 83 percent of plan sponsors reported complete plan-to-dispenser connectivity. Only 5 percent of plan sponsors reported no plans to implement the plan-to-dispenser standard. All of these plan sponsors are PACE plan sponsors.

Although CMS educational activities in the fall of 2008 may have increased plan sponsor awareness of requirements, complete connectivity remains a problem likely because of plan sponsors' technical difficulties with the batch data upload process. Most plan sponsors indicated that their implementation is limited because of system incompatibility with Formulary & Benefits Standard 1.0 rather than a lack of knowledge about requirements.

Based on the results of our review, CMS should:

Ensure that plan sponsors completely implement the plan-to-prescriber and plan-to-dispenser standards

To ensure plan sponsor compliance with requirements to implement e-prescribing standards, CMS could implement all of the following:

- Continue to educate plan sponsors about e-prescribing standards requirements. In September 2008, CMS issued a memorandum clarifying e-prescribing requirements for plan sponsors. In October 2008, CMS held an e-prescribing conference with educational sessions and presentations about e-prescribing standards and the effective date for standards implementation. In addition, CMS has conducted e-prescribing open door forums to educate plan sponsors and prescribers about e-prescribing requirements.

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- Clarify the e-prescribing standard exemption for closed prescribing systems and the way to claim the exemption when appropriate. CMS should consider clarifying the exemption with PACE plan sponsors specifically.
- Use available compliance mechanisms when necessary, such as corrective action plans and civil monetary penalties, to bring plan sponsors into compliance.

Collaborate with plan sponsors and industry representatives to address barriers to full implementation of Formulary & Benefits Standard 1.0

CMS should collaborate with plan sponsors, PBMs, and standards-development organizations to address the batch processing problems identified in this report. CMS could consider pilot-testing a real-time standard that enables plan sponsors to transmit beneficiary-specific formulary and benefits information. Several plan sponsors and PBMs indicated that a real-time formulary and benefits standard would enable them to transmit comprehensive beneficiary-specific formulary and benefits information to prescribers. Currently, a few industry organizations are developing a real-time formulary and benefits standard. CMS acknowledged the benefits of a real-time formulary and benefits standard in the comment and response section of the April 2008 final e-prescribing rule.

AGENCY COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

CMS concurred with each of our recommendations. To address our recommendations, CMS will continue to educate plan sponsors about e-prescribing requirements. If necessary, CMS will also use available compliance mechanisms to bring plan sponsors into compliance. In addition, CMS plans to clarify the e-prescribing requirements for PACE plan sponsors. In the 2011 PACE application, CMS will formally waive the e-prescribing requirements for PACE plan sponsors. Finally, CMS plans to continue collaboration with the National Council of Prescription Drug Program, Inc., to continually update and develop new e-prescribing standards.

Although CMS concurred with our recommendations, it asserted there were significant methodological limitations with our data collection and analysis, resulting in inflated findings of plan sponsor noncompliance with e-prescribing standards.

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Specifically, CMS asserted that our results would have likely been different if our plan sponsor survey had been conducted closer to the implementation deadline. First, CMS stated that our surveys did not capture the impact of CMS's plan sponsor e-prescribing educational activities, which clarified that all standards had to be adopted. Second, CMS stated that, at the time of our survey, plan sponsors did not fully appreciate the potential impact of Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) e-prescribing incentive payments. As a result, CMS stated it believes that, after our survey, more plan sponsors may have decided to comply with e-prescribing requirements to prepare for the increasing number of prescribers adopting e-prescribing to obtain MIPPA incentive payments.

If we had conducted our survey at a later date, we acknowledge that implementation rates could have risen. However, we do not believe that the results reported here are inflated. While CMS's educational activities clarified requirements and MIPPA may have increased the desire to implement the standards, neither would have changed the technical difficulties reported in our findings. The primary reason plan sponsors reported incomplete implementation of the standards was technical difficulties with Formulary & Benefits Standard 1.0, which CMS's educational activities did not address.

CMS also noted that it does not consider plan sponsors to be out of compliance with the e-prescribing standards if prescribers do not request e-prescribing information. Specifically, CMS does not expect many prescribers to request information on the Formulary Alternatives List because this information is available through other sources. According to CMS's response, as long as no prescribers request the Formulary Alternatives List, then a plan sponsor is not out of compliance for not implementing the Formulary Alternatives List.

We note that the primary focus of this study was not on plan sponsors' compliance with the e-prescribing standards. Rather, this study focused on plan sponsors' ability to support and implement the foundation for e-prescribing connectivity between plan sponsors and prescribers. Because this study is focused on plan sponsors' ability to support e-prescribing connectivity with prescribers, our findings describe the completeness of plan sponsors' implementation of the e-prescribing standards that CMS identified as the foundation for connectivity.

In addition, although information in the Formulary Alternatives List may be available from other sources, this and other e-prescribing standards are

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still required if at least one prescriber requests the information provided by those standards, according to CMS guidance. Further, our findings show nonimplementation of the Formulary Alternatives List is not the main contributor to plan sponsors' reported problems with Formulary & Benefits Standard 1.0. Plan sponsors reported higher implementation of the Formulary Alternatives List and the Formulary Status List than the Copayment List and the Coverage List. Plan sponsors reported that the batch data upload process prevented them from fully implementing the Copayment List and the Coverage List.

Finally, CMS recommended that we remove PACE plan sponsors from our findings because CMS has now waived the e-prescribing requirement for PACE plan sponsors. We did not remove PACE plan sponsors from our findings because, at the time of our data collection, PACE plan sponsors were required to implement e-prescribing standards. In addition, our findings show that PACE plan sponsors were confused about the e-prescribing standards. Based on this finding, we suggested that CMS clarify requirements for PACE plan sponsors, which it has now done.

For the full text of CMS's comments, see Appendix D.

Formulary & Benefits Standard 1.0 Components

Formulary & Benefits Standard 1.0 is composed of four components: Formulary Status List, Formulary Alternatives List, Coverage List, and Copayment List.³⁰ Each component includes several elements that can assist prescribers in prescribing the most appropriate drug for a beneficiary.

The four components are:³¹

1. **Formulary Status List:** This component provides prescribers with the drug name and indicates whether the drug is preferred, not preferred, or not reimbursable according to a plan's formulary.
2. **Formulary Alternatives List:** This component provides prescribers with a list of alternative drugs, such as generic drugs, low-cost alternatives, and therapeutically equivalent alternatives that are covered for a beneficiary.
3. **Coverage List:** This component provides prescribers with information on the conditions under which the patient's policy covers a medication, such as prior authorization requirements, step therapy lists,³² quantity limits, age limits, and gender limits.
4. **Copayment List:** This component provides the cost of the prescription to the beneficiary, such as dollar or percentage copayment amounts, copayment tiers (higher tiers mean higher copayments), and prescription quantity covered under the copayment.

³⁰ National Council for Prescription Drug Programs, Inc. (NCPDP). NCPDP Formulary and Benefits Standard Implementation Guide excerpt, version 2.0, May 2008.

³¹ Ibid.

³² A step therapy list describes a progression of drugs for a medical condition, beginning with the most cost-effective and safest medications and then moving on to more costly or risky medications if necessary.

Analysis Categories for Plan-to-Prescriber and Plan-to-Dispenser Connectivity

Table B1: Detailed Description of Plan-to-Prescriber and Plan-to-Dispenser Connectivity			
E-Prescribing Connectivity	Implementation Category	Implementation Phase	Description
Plan-to-Prescriber	Complete connectivity	Implemented	Plan sponsor has completely implemented Accredited Standards Committee (ASC) X12N 270/271, SCRIPT 8.1, and all four components of Formulary & Benefits Standard 1.0.
		Planning implementation	Plan sponsor has plans to completely implement all three plan-to-prescriber standards. Plan sponsor may have implemented one or two standards and is planning to implement the rest. For example, the plan sponsor has completely implemented ASC X12N 270/271 and is planning to implement SCRIPT 8.1 and all four components of Formulary & Benefits Standard 1.0.
	Partial connectivity	Implemented	Plan sponsor has implemented some, but not all, of the plan-to-prescriber standards and has no plans to implement the other standards. For example, the plan sponsor has implemented ASC X12N 270/271 and SCRIPT 8.1 but is not planning to implement Formulary & Benefits Standard 1.0.
		Planning implementation	Plan sponsor has plans to implement some, but not all, of the plan-to-prescriber standards. For example, the plan sponsor plans to implement ASC X12N 270/271, SCRIPT 8.1, and two of the four components of Formulary & Benefits Standard 1.0. It has no plans to implement the remaining two Formulary & Benefits Standard 1.0 components.
	No connectivity	N/A	Plan sponsor has no plans to implement ASC X12N 270/271, SCRIPT 8.1, or any of the four components of Formulary & Benefits Standard 1.0.
	Missing information	N/A	Plan sponsor did not answer any plan-to-prescriber questions.
Plan-to-Dispenser	Complete connectivity	Implemented	Plan sponsor has implemented Telecommunication 5.1.
		Planning implementation	Plan sponsor has plans to implement Telecommunication 5.1.
	No connectivity	N/A	Plan sponsor has no plans to implement Telecommunication 5.1.
	Missing information	N/A	Plan sponsor did not answer the plan-to-dispenser question.

Source: Office of Inspector General (OIG) analysis of survey data, 2008.

Analysis Categories for the Formulary & Benefits Standard 1.0 Components

To assess plan sponsor implementation of each of the four Formulary & Benefits Standard 1.0 components, we divided plan sponsors into four implementation categories. Table B2 provides a detailed description of the categories for the Formulary & Benefits Standard 1.0 components: Formulary Status List, Formulary Alternatives List, Coverage List, and Copayment List.

Table B2: Detailed Description of Implementation Categories for the Formulary & Benefits Standard 1.0 Components

Implementation Category	Implementation Phase	Description
Complete	Implemented	Plan sponsor has implemented all elements of a component.
	Planning implementation	Plan sponsor plans to completely implement all elements of a component.
Partial	Implemented	Plan sponsor has completely implemented some, but not all, of the elements of a component. For example, a plan sponsor that has partially implemented Coverage List has implemented quantity limits and age limits but not the other Coverage List elements.
	Planning implementation	N/A – We did not ask plan sponsors to indicate plans to partially implement each component.
Not planning	N/A	Plan sponsor has no plans to implement any elements of a component.
Missing information	N/A	Plan sponsor did not answer any component questions.

Source: OIG analysis of Formulary & Benefits Standard 1.0, 2008.

Implementation of Plan-to-Prescriber Standards

More plan sponsors reported complete implementation of Accredited Standards Committee (ASC) X12N 270/271 and SCRIPT 8.1 than Formulary & Benefits Standard 1.0. Table C1 shows the implementation status of each plan-to-prescriber standard.

Table C1: Plan Sponsors' Current and Planned Implementation of Plan-to-Prescriber Standards

Standard	Complete Implementation		Partial Implementation		Not Planning Implementation	Missing Information
	Implemented	Planning Implementation	Implemented	Planning Implementation		
ASC X12N 270/271 (n = 262)	58%	18%	N/A	N/A	20%	4%
SCRIPT 8.1 (n = 262)	45%	34%	N/A	N/A	16%	5%
Formulary & Benefits Standard 1.0* (n = 262)	0.4%	8%	46%	20%	16%	9%

* Total does not add to 100 percent because of rounding.

Source: Office of Inspector General (OIG) analysis of survey data, 2008.

ASC X12N 270/271. Fifty-eight percent of plan sponsors reported that they had completely implemented ASC X12N 270/271. These plan sponsors can respond to prescribers' requests about beneficiary eligibility at the point of care. Prescribers can use this information to identify beneficiaries' eligibility for drug benefits. As a result, a prescriber may see administrative cost savings because of fewer callbacks from a dispenser requesting permission to change the prescription to a drug that is covered for a beneficiary.

An additional 18 percent of plan sponsors reported plans to completely implement ASC X12N 270/271. Of these plan sponsors, 86 percent reported plans to implement the standard by April 2009. Nine percent reported plans to implement the standard after April 2009 but did not provide specific dates for implementation. Five percent of plan sponsors did not provide any information about their timeframe for implementing this standard. Plan sponsors did not provide reasons why they had not implemented ASC X12N 270/271 by the January 2006 deadline.

Twenty percent of plan sponsors reported no plans to implement ASC X12N 270/271. Additionally, 4 percent of plan sponsors did not reply to questions about this standard.

SCRIPT 8.1. Forty-five percent of plan sponsors reported that they had completely implemented SCRIPT 8.1. These plan sponsors can provide

prescribers with a list of Part D drugs dispensed to beneficiaries. Prescribers can use this medication history to reduce adverse drug events, such as drug-to-drug allergies or interactions.

An additional 34 percent of plan sponsors reported plans to completely implement SCRIPT 8.1. Of these plan sponsors, 82 percent reported plans to implement SCRIPT 8.1 by the April 2009 deadline. Sixteen percent plan to implement the standard after April 2009 but did not provide specific dates for implementation. Two percent of plan sponsors did not provide any information about their timeframe for implementing this standard.

Sixteen percent of plan sponsors reported no plans to implement SCRIPT 8.1. Additionally, 5 percent of plan sponsors did not reply to questions about this standard.

Formulary & Benefits Standard 1.0. One plan sponsor, or less than 1 percent of plan sponsors, reported that it had completely implemented all components of Formulary & Benefits Standard 1.0. This plan sponsor can provide prescribers with complete formulary and benefits information for beneficiaries. Prescribers can use this information to save beneficiaries money by identifying and prescribing low-cost, alternative drugs. Prescribers and dispensers may also save on administrative costs by reducing callbacks.

An additional 8 percent of plan sponsors reported plans to completely implement all elements of Formulary & Benefits Standard 1.0. Of these plan sponsors, 64 percent planned to completely implement the standard by the April 2009 deadline. Fourteen percent plan implementation after April 2009 but did not provide specific dates. Twenty-two percent of plan sponsors did not provide any information about their timeframe for implementing this standard.

Sixteen percent of plan sponsors reported no plans to implement Formulary & Benefits Standard 1.0. Additionally, 9 percent of plan sponsors did not reply to questions about this standard.

Implementation Detail for Formulary & Benefits Standard 1.0 Components

Table C2 shows plan sponsors' implementation status for each Formulary & Benefits Standard 1.0 component.

Table C2: Plan Sponsors' Implementation of Formulary & Benefits Standard 1.0 Components

Component	Complete Implementation		Partial Implementation		Not Planning Implementation	Missing Information
	Implemented	Planning Implementation	Implemented	Planning Implementation		
Formulary Status List (n = 262)	51%	20%	7%	N/A	2%	20%
Formulary Alternatives List (n = 262)	23%	33%	0%	N/A	24%	20%
Coverage List* (n = 262)	10%	20%	37%	N/A	13%	21%
Copayment List* (n = 262)	3%	20%	14%	N/A	42%	20%

* Totals do not add to 100 percent because of rounding.

Source: OIG analysis of survey data, 2008.

Agency Comments



DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services

Administrator
Washington, DC 20201

DATE: AUG 21 2009

TO: Daniel R. Levinson
Inspector General

FROM: Charlene Frizzera
Acting Administrator

SUBJECT: Office of Inspector General (OIG) Draft Report: "Medicare Part D E-Prescribing Standards: Early Assessment Shows Partial Connectivity" (OEI-05-08-00320)

Thank you for the opportunity to review and comment on this OIG draft report discussing the extent of Medicare Part D sponsors' implementation of electronic prescribing (e-prescribing) standards to support connectivity with prescribers and dispensers. The Centers for Medicare & Medicaid Services (CMS) fully supports the advancement of e-prescribing and is committed to ensuring that the Part D sponsors support the adopted Part D e-prescribing standards.

The CMS generally concurs with the report's recommendations. However, we believe that there were significant methodological limitations in the data collection and analysis utilized in this report, which inflated the findings related to sponsor non-compliance with our e-prescribing standards. As the sponsor survey used in this report was conducted 7 months prior to the deadline for compliance with two of the e-prescribing standards examined in this report, the report failed to capture the impact of the sponsor and provider e-prescribing education and outreach activities that occurred after the date upon which the survey was complete. As discussed in more detail below, the results would have likely been different if the survey was conducted closer to the implementation deadline.

The report findings related to the National Council of Prescription Drug Programs (NCPDP) Formulary & Benefits Standard, Version 1, Release 0 (NCPDP Formulary and Benefits 1.0) are the main driver behind the conclusion that most sponsors are only partially compliant with 'provider to plan' communication standards. CMS believes it is important to clarify two issues with the findings in this report with respect to the discussion of this standard in the report:

- First, the findings regarding implementation status reflect initial confusion among Part D sponsors that CMS addressed in a September 2008 memorandum to Part D sponsors. Further clarification was provided at the October 2008 national e-prescribing conference. Specifically, many Part D sponsors initially believed that they only needed to support transactions using the Formulary Status List function of the NCPDP Formulary & Benefits 1.0 standard. The September 2008 memorandum clarified that Part D sponsors

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also needed to support the other functions that are addressed by the NCPDP Formulary and Benefits 1.0 standard. Consequently, we believe that the survey results regarding Part D sponsors' implementation plans would have differed significantly if the survey had been performed after the updated guidance was issued, and therefore believe that the findings are not an accurate reflection of actual Part D sponsor preparedness for the April 2009 deadline.

- Second, we also clarified in our September 2008 memorandum that “supporting” the NCPDP Formulary and Benefits 1.0 standard means that Part D sponsors were capable of sending and receiving transactions using the adopted standard *if electronic transactions using the functions supported by that standard were requested*. We specifically highlighted the Formulary Alternatives List as one function that likely would not be requested in an electronic transaction by prescribers because e-prescribing intermediaries already make this same information available through alternative means. In other words, the industry's current electronic prescribing practices may differ from what had been anticipated by the original standard development process, but those practices remain compliant with the adopted standards. In some cases, provider point-of-care systems have adopted processes based on data sources that provide what otherwise would have had to be obtained from Part D sponsors through electronic transactions using functions that are covered by the adopted Part D e-prescribing standards. In these instances, use of transactions utilizing the adopted standards would duplicate data already obtained through other means that are not subject to any Part D e-prescribing standards. As was implied in the report, we would not consider Part D sponsors that are not utilizing the Formulary Alternatives List function of the adopted standard to be out of compliance with the adopted standard if the Part D sponsors are not receiving any requests for electronic transactions that could be conducted using that function.

OIG Recommendation

The OIG recommends that CMS ensure that plan sponsors completely implement the plan-to-prescriber and plan-to-dispenser standards.

CMS Response

The CMS concurs with this recommendation, with the clarifications noted above. We agree that CMS should ensure that plan sponsors support and utilize the adopted standards when conducting electronic transactions that can be conducted using the functions within the standards. The report notes the steps that CMS has already taken to educate and clarify our e-prescribing requirements for Part D sponsors and we will continue to monitor the implementation and utilization of Part D e-prescribing standards to determine if further guidance is needed. If necessary, CMS will use available compliance mechanisms to bring sponsors into compliance.

We also can confirm that CMS has formally waived the Part D e-prescribing requirements for Program for All-Inclusive Care for the Elderly (PACE) programs. While some PACE programs indicated in the report that the e-prescribing requirements did not apply to them because they had

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a closed prescribing system, CMS, in accordance with our authority under Federal regulations at 42 CFR 423.458, has explicitly waived the requirements found at 42 CFR 423.159(c) and 42 CFR 423.160(a) as applied to PACE programs. The waiver of these requirements will be included in the 2011 PACE application. Therefore, we recommend that OIG adjust their findings to exclude PACE programs.

OIG Recommendation

The OIG recommends that CMS collaborate with plan sponsors and industry representatives to address barriers to full implementation of the Formulary and Benefits Standard 1.0.

CMS Response

The CMS concurs with this recommendation. CMS actively participates at the NCPDP workgroup meetings and on the NCPDP task groups that are continually working on updating and developing new electronic standards, including e-prescribing standards. However, OIG should not interpret the lack of a real-time Formulary and Benefits standard as a barrier to supporting the existing NCPDP Formulary and Benefits 1.0 Part D standard. We adopted the NCPDP Formulary and Benefit 1.0 knowing, as with all the electronic standards we adopt, that we may need to adopt new standards in the future as the state of the art changes. While a future real-time standard may allow for better and timelier communication of formulary and benefit information, it does not justify Part D sponsors' non-support of the current standard, nor does it create a barrier to the implementation of the adopted standards.

Other Comments:

1. **Page iii:** The CMS has concerns that pilot-testing could delay implementation as providers who have already adopted systems will have to update their systems, which may cause the provider community to delay implementation if they perceive that the requirements/standards are being used before being fully developed.
2. **Page 5:** The statement: "CMS has made efforts to educate" is misleading. CMS did educate and was still educating during this assessment. The statement appears to minimize the effort.
3. **Page 11:** While our assessment took place ... to implement them." CMS disagrees with this conclusion. Seven months prior to 4/1/09 would be 9/1/08. At this time, the impact of the Medicare Improvements for Patients and Providers Act (MIPPA) was likely not fully appreciated. While the eRx incentive program was announced, details of the actual program were not. Accordingly, the plan sponsors may not have been able to appreciate/estimate the magnitude in terms of numbers of providers who would be adopting/using eRx as a result of MIPPA. An under-estimate of this number may have influenced the plan's decision to delay or not adopt all of the new eRx standards which took effect in April, 2009. Thus, again, we believe that the survey results regarding Part D sponsors' plans to implement would have differed significantly if the survey had been performed a little later in the year and, as a result, do not believe that the survey results

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are an accurate reflection of actual Part D sponsor preparedness for the April 2009 deadline.

4. **Page 15, 5th line from the bottom:** CMS believes the sponsors referred to in this passage intended to say “alternative” rather than alterative, which means healing, therapeutic.

We appreciate the effort that went into this report. Again, we thank you for the opportunity to review and comment.



A C K N O W L E D G M E N T S

This report was prepared under the direction of Ann Maxwell, Regional Inspector General for Evaluation and Inspections in the Chicago regional office, and Thomas Komaniecki, Deputy Regional Inspector General.

Kelly Waldhoff served as the project leader for this study. Other principal Office of Evaluation and Inspections staff from the Chicago regional office who contributed to the report include Suzanne Bailey, Abby Lopez, and Michelle Park. Other principal central office staff who contributed include Robert Gibbons, Kevin Manley, and Matt McMullen.