DEPARTMENT OF HEALTH & HUMAN SERVICES
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CENTER FOR DRUG and HEALTH PLAN CHOICE

TO: Part D Sponsors

FROM: Cynthia G. Tudor, Ph.D., Director, Medicare Drug Benefit and C & D Data Group

SUBJECT: Supporting Electronic Prescribing under Medicare Part D

DATE: September 19, 2008

The purpose of this communication is to (1) reiterate the requirement for Part D sponsors to support e-prescribing, particularly with respect to the “initial” e-prescribing standards that become effective April 1, 2009, and to (2) suggest a review of network pharmacy dispensing fees for appropriate consideration of new e-prescribing costs.

Beginning in 2009, the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) will require the Centers for Medicare & Medicaid Services (CMS) to provide incentive payments to eligible providers who are successful electronic prescribers. Successful electronic prescribers will be required to utilize qualified electronic prescribing (e-prescribing) systems in compliance with e-prescribing standards established for the Medicare Part D program. Given our expectation of a significant increase in e-prescribing beginning in 2009 as a result of the new MIPPA incentives, CMS is providing this reminder on the Part D e-prescribing standards that will become effective April 1, 2009 in order to promote consistent implementation and application across the Part D program, and to establish clear expectations for Part D sponsors.

Background

As required by the MMA and Chapter 7 of the Prescription Drug Benefit Manual, Part D sponsors are required to establish electronic prescription drug programs to provide for electronic transmittal of certain information to the prescribing provider and the dispensing pharmacy and pharmacist. In doing so, Part D sponsors must support Part D e-prescribing standards when such standards become effective.

Foundation Standards

On November 7, 2005, CMS published its first E-prescribing and Prescription Drug Program final rule that adopted the "foundation standards" for e-prescribing under Medicare Part D. The foundation standards have been in effect since January 1, 2006. The foundation standards adopted in this final rule were:

- The National Council for Prescription Drug Programs (NCPDP) SCRIPT standard, Implementation Guide, Version 5, Release 0 (NCPDP SCRIPT 5.0)[1] for communicating prescription or prescription-related information between prescribers and dispensers for certain transactions;
- Accredited Standards Committee (ASC) X12N 270/271 Health Care Eligibility Benefit Inquiry and Response, Version 4010 and Addenda to Health Care Eligibility Benefit Inquiry and Response, Version 4010A1 for communicating eligibility information between Medicare Part D plan sponsors and prescribers; and
- NCPDP Telecommunication Standard Specification, Version 5, Release 1 and equivalent NCPDP Batch Standard Batch Implementation Guide, Version 1, Release 1 supporting Telecommunication Standard Implementation Guide, Version 5, Release 1 for NCPDP Data Record in the Detail Data Record for communicating eligibility information between Medicare Part D plan sponsors and dispensers.

Initial Standards

On April 7, 2008, CMS published another final rule to adopt additional uniform standards for medication history, formulary and benefits, and fill status for the Medicare Part D e-prescribing program. These additional standards are referred to as the "initial standards" for e-prescribing under Medicare Part D. These initial standards build on the foundation standards that were established in the E-prescribing and Prescription Drug Program final rule published on November 7, 2005. The initial standards are:

- NCPDP Formulary and Benefits Standard, Implementation Guide, Version 1, Release 0 (NCPDP Formulary and Benefits 1.0) for transmitting formulary and benefits information between prescribers and Medicare Part D plan sponsors;
- NCPDP Prescriber/Pharmacist Interface SCRIPT standard, Implementation Guide, Version 8, Release 1 (NCPDP SCRIPT 8.1)
    - to provide for the communication of the Fill Status Notification transaction between prescribers and dispensers
    - to provide for communication of the Medication History transaction among Medicare Part D plan sponsors, prescribers and dispensers; and
- The National Provider Identifier (NPI) to identify an individual health care provider in electronically transmitted prescriptions or prescription related materials.

While the foundation standards are the only e-prescribing standards Part D sponsors will be required to support when the provisions of MIPPA become effective on January 1, 2009, Part D sponsors will be required to support the initial standards as well

[1] The NCPDP SCRIPT 8.1 standard was recognized as a "backward compatible" update of the adopted NCPDP SCRIPT 5.0 standard on June 23, 2006. The NCPDP SCRIPT 5.0 foundation standard will be retired and replaced with the NCPDP SCRIPT 8.1 standard as of April 1, 2009.

beginning April 1, 2009. The following guidance clarifies CMS' expectations for Part D sponsors and their contracted network pharmacies as of April 1, 2009.

Part D e-Prescribing requirements as of April 1, 2009:

Section 101 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) requires Part D sponsors to establish electronic prescription drug programs that provide for the electronic transmittal of prescription and prescription-related information to the prescriber and the dispenser in accordance with final standards specified by CMS. This includes information on eligibility, benefits (including the drugs included in the applicable formulary, any tiered formulary structure, and any requirements for prior authorization), the drug being prescribed or dispensed and other drugs listed in the medication history, as well as the availability of lower cost and therapeutically appropriate alternatives (if any). See § 1860D-4(e) of the MMA. The foundation standards identified standards for electronically transmitting eligibility information from the Part D sponsor to the prescriber or dispenser and for transmitting prescription information between prescriber and dispenser. The initial standards include, among others, the standards for Part D sponsors to electronically transmit medication history and formulary & benefit information to prescribers.

Part D sponsors are required to comply with and support the final initial standards as of April 1, 2009. This means Part D sponsors must be prepared to provide medication history information via transactions using the NCPDP SCRIPT 8.1 medication history standard and all formulary & benefit information via the NCPDP Formulary and Benefit 1.0 standard as of April 1, 2009. While we recognize that Part D sponsors currently might not support transactions using the initial Part D e-prescribing standards for their commercial or Part D business, we note that they will need to do so for electronic transactions for Medicare Part D covered drugs for Medicare Part D eligible individuals as of April 1, 2009

While the foundation standards were adopted based on findings of adequate industry experience, the initial Part D e-prescribing standards were adopted based upon pilot-testing that confirmed that the standards were capable of performing their intended functions. The industry generally has less experience with the initial standards and we are aware that there are various levels of support of these standards in current commercial operations by Part D sponsors. CMS is concerned that without additional guidance, Part D sponsors might not uniformly support the initial standards. Therefore, CMS believes it is necessary to clarify the following requirements for supporting the initial standards as of April 1, 2009 to ensure that all Part D sponsors consistently use and support the initial standards.

1. <u>NCPDP Formulary and Benefits 1.0 standard</u>

The NCPDP Formulary and Benefits 1.0 standard includes five separate files for providing formulary or benefit information to the prescriber. These files are:

- Formulary Status List
- Formulary Alternatives List
- Benefit Coverage List
- Benefit Copay List
- Drug Classification List

CMS clarifies that Part D sponsors must be capable of sending all of these files electronically using the adopted standard if such information is requested as of April 1, 2009. This means that Part D sponsors must have all necessary vendor contracts and systems in place to receive and transmit these electronic transactions in compliance with the standard if prescribers are requesting this information. We also clarify that this means that Part D sponsors must be prepared to electronically send all the conditional fields for all these files using the adopted standard if such information is requested by prescribers. For example, Part D sponsors must provide actual product-specific quantity limits if a product is subject to a quantity limit when transmitting the Benefit Coverage List (if requested by the prescriber).

However, we recognize that prescribers might not currently (or after April 1, 2009) need or request all Formulary and Benefit files because their point-of-care software vendors already provide equivalent information. For example, it is our understanding that point-of-care software vendors typically provide their clients with commercially available drug classification lists thereby negating the need to obtain payer-specific drug classifications. We also are aware that point-of-care software vendors often display preferred formulary alternatives using the information provided in the Formulary Status List and Benefit Copay List. Providers may, therefore, not need to receive the Formulary Alternatives List from the Part D sponsor. Therefore, we expect that all Part D sponsors will provide the Formulary Status List, the Benefit Coverage List and the Benefit Copay List electronically using the adopted Part D e-prescribing standards upon request as of April 1, 2009 because this information is only available from Part D sponsors or their intermediaries. On the other hand, we anticipate that Part D sponsors might not actually be asked to provide the Formulary Alternatives List and the Drug Classification Lists in those situations where contracts with point-of-care software vendors and/or other e-prescribing intermediaries arrange for this information to be made available to prescribers through alternative means.

2. NCPDP SCRIPT 8.1 Medication History standard

CMS clarifies that Part D sponsors must support the NCPDP SCRIPT 8.1 Medication History transaction by providing medication history from the current Part D sponsor's (or its Pharmacy Benefit Manager's (PBM's) or other formulary support contractor's) medication history files. CMS does not require Part D sponsors to ensure that prescribers are provided medication history files from pharmacies.

3. NCPDP SCRIPT 8.1 Prescription Fill Status Notification (RxFill) standard

While it lacked adequate industry experience for adoption as one of the foundation standards, the NCPDP SCRIPT RxFill standard for the fill status transaction was adopted as an initial standard for the reasons explained in the April 7, 2008 final rule. The RxFill standard is part of the SCRIPT 8.1 standard. It is used for fill status transactions between prescribers and pharmacies.

While Part D sponsors must support the Part D e-prescribing standards, e-prescribing is voluntary for pharmacies. However, pharmacies that choose to conduct e-prescribing for Medicare Part D covered drugs that are prescribed to Medicare Part D eligible individuals must do so in compliance with the Part D e-prescribing standards. Accordingly, if a pharmacy provides fill status on e-prescriptions, it must do so in compliance with the NCPDP SCRIPT 8.1 RxFill standard. CMS expects that only those pharmacies with agreements with point-of-care vendors or their intermediaries to use the NCPDP SCRIPT 8.1 RxFill standard for fill status transactions will utilize this function when processing e-prescriptions. It is our understanding that RxFill is not widely used in industry today because barriers exist to effectively implement and utilize the transaction, and moreover, the NCPDP SCRIPT 8.1 Medication History transaction already provides similar information to the prescriber. Therefore, although the transaction standard is available, CMS does not expect it to be widely used until the industry further addresses implementation issues.

Part D sponsors must support the Part D e-prescribing standards that involve transactions between prescribers and their network pharmacies by ensuring that their pharmacy contracts require the pharmacies to comply with the Part D e-prescribing standards when receiving or transmitting electronic prescriptions (e-prescriptions) or prescription related information. Although Part D sponsors are not required to pay for standard e-prescribing transactions between prescribers and pharmacies, such e-prescribing transaction costs incurred by their network pharmacies are legitimate Part D overhead costs that should be a consideration in setting network dispensing fees.

4. Individual Prescriber NPI

The NPI was adopted as an initial Part D e-prescribing standard. Providers are required to use their NPI as an identifier in e-prescribing Part D covered Drugs for Part D eligible individuals. While the regulatory text simply identifies NPI as a Part D e-prescribing standard, it is clear from the preamble that we adopted NPI as the "identifier of individual, non-institutional health care providers." Therefore, in practice, the NPI must be the prescriber's individual NPI. We expect that beginning April 1, 2009, all compliant e-prescribing transactions will include the providers' individual NPIs as identifiers. Although the NPI requirement does not become effective until April 1, 2009, we would expect that e-prescribers will generally provide an NPI prior to that date, as opposed to alternative prescriber identifiers such as DEA numbers.

Ensuring adequate network pharmacy participation to support e-prescribing under Medicare Part D

The success of e-prescribing under the Medicare Part D program largely depends upon the implementation of e-prescribing by network pharmacies. The program will not be successful -- and e-prescribers will become frustrated -- if Part D participating pharmacies are not willing or prepared to implement e-prescribing. Accordingly, CMS expects Part D sponsors to facilitate adoption of e-prescribing by not only utilizing the Part D e-prescribing standards in transactions that originate with the sponsor and supporting receipt of compliant transactions from dispensers and prescribers, but also by working with their network pharmacies to ensure that such pharmacies have e-prescribing systems in place that are capable of sending and receiving transactions that are compliant with the Part D e-prescribing standards. The spread of such systems will ensure that providers that wish to conduct e-prescribing will be able to do so with the pharmacy of their patient's choice. (Prescriptions that are electronically transmitted and received via fax machine are not subject to the Part D e-prescribing standards. Prescriptions that are generated by a computer but received a fax machine are electronic transactions. They are subject to the Part D e-prescribing rules for "computer-generated facsimiles").

While CMS believes a significant number of pharmacies currently support e-prescribing and comply with the Part D e-prescribing standards, CMS understands Part D pharmacy access standards may be jeopardized if sponsors were to contractually mandate all network pharmacies to support e-prescribing as a condition of participation in their network. Thus, as outlined in Chapter 7 of the Prescription Drug Benefit Manual (Section 50.1), Part D sponsors must allow for exceptions to network pharmacy support for e-prescribing when it is either impractical or otherwise could jeopardize beneficiary access.

CMS recognizes that up-front implementation costs, current low prescriber utilization, and transaction fees associated with transmitting and receiving e-prescriptions are barriers to the ability and willingness of some pharmacies to implement e-prescribing for the Part D program. Aligning pharmacies' and Part D sponsors' interests to support e-prescribing will help overcome these barriers.

CMS considers the costs incurred by network pharmacies to implement e-prescribing and transmit and receive e-prescribing transactions for Part D covered drugs prescribed to Part D eligible individuals to be legitimate Part D overhead costs that should be a factor in developing dispensing fees. We believe that it is unlikely that dispensing fees that were negotiated prior to a pharmacy's implementation of e-prescribing factored into these costs. Therefore, we would expect Part D sponsors to review network dispensing fees to ensure they appropriately reimburse pharmacies for these new costs.

Alternatively, Part D sponsors could both address these new costs and incentivize pharmacies to implement e-prescribing by paying differential dispensing fees. In other

words, specific incentive amounts could be added to claim payments associated with e-prescriptions and such amounts would be reported as additional dispensing fees to CMS. Such incentive fees could also explicitly serve to align pharmacy incentives with plan incentives to acquire accurate individual prescriber NPIs and prescription origin codes that will be required on PDEs. CMS strongly encourages Part D sponsors to consider negotiating differential dispensing (or incentive) fees for e-prescriptions in order to align incentives with their network pharmacies to fully support and comply with the Part D e-prescribing standards.