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# Department of Health and Human Services

## 45 CFR Part 162

## Health Insurance Reform; Modifications to the Health Insurance Portability and Accountability Act (HIPAA); Final Rules

EXHIBIT
JOINT-49

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Office of the Secretary**

**45 CFR Part 162**

**[CMS–0009–F]**

**RIN 0938–AM50**

# Health Insurance Reform; Modifications to the Health Insurance Portability and Accountability Act (HIPAA) Electronic Transaction Standards

**AGENCY:** Office of the Secretary, HHS.

**ACTION:** Final rule.

**SUMMARY:** This final rule adopts updated versions of the standards for electronic transactions originally adopted under the Administrative Simplification subtitle of the Health Insurance Portability and Accountability Act of 1996 (HIPAA). This final rule also adopts a transaction standard for Medicaid pharmacy subrogation. In addition, this final rule adopts two standards for billing retail pharmacy supplies and professional services, and clarifies who the ''senders'' and ''receivers'' are in the descriptions of certain transactions.

**DATES:** *Effective Dates:* These regulations are effective March 17, 2009 except for the provisions of 45 CFR part 162 Subpart S, which are effective January 1, 2010. The incorporation by reference of certain publications listed in the regulations is approved by the Director of the Federal Register as of March 17, 2009.

*Compliance Dates:* Compliance with the provisions of §§ 162.1102(c), 162.1202(c), 162.1302(c), 162.1402(c), 162.1502(c), 162.1602(c), 162.1702(c), and 162.1802(c) is required on January 1, 2012. Compliance with the provisions of § 162.1902 is required on January 1, 2013.

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## I. Background

HIPAA mandated the adoption of standards for electronically conducting certain health care administrative transactions between certain entities. Through subtitle F of title II of HIPAA, the Congress added to title XI of the Social Security Act (the Act) a new Part C, entitled ''Administrative Simplification.'' Part C of title XI of the Act now consists of sections 1171 through 1180. These sections define various terms and impose several requirements on HHS, health plans, health care clearinghouses, and certain health care providers concerning the electronic transmission of health information. On August 17, 2000, we published a final rule entitled, ''Health Insurance Reform: Standards for Electronic Transactions'' in the **Federal Register** (65 FR 50312) (hereinafter referred to as the Transactions and Code Sets rule). That rule implemented some of the HIPAA Administrative Simplification requirements by adopting standards for eight electronic transactions and for code sets to be used in those transactions. Those transactions were: Health care claims or equivalent encounter information; health care payment and remittance advice; coordination of benefits; eligibility for a health plan; health care claim status; enrollment and disenrollment in a health plan; referral certification and authorization; and health plan premium payments. We defined these transactions and specified the adopted standards at 45 CFR part 162, subparts I and K through R.

Since the time of compliance with the first set of HIPAA standards, a number of technical issues with the standards, including issues resulting from new business needs, have been identified. Industry stakeholders submitted hundreds of change requests to the standards maintenance organizations, with recommendations for improvements to the standards. These requests were considered, and many were accepted, resulting in the development and approval of newer versions of the standards for electronic transactions. However, covered entities are not permitted to use those newer versions until the Secretary of Health and Human Services (HHS) adopts them by regulation for HIPAA transactions.

In addition to technical issues and business developments necessitating consideration of the new versions of the standards, there remain a number of unresolved policy issues that were identified by the industry early in the implementation period for the first set of standards, and those issues were never addressed through regulation. This final rule addresses those outstanding issues.

We refer readers to review the following regulations for a more detailed discussion of the changes to the standards for electronic transactions; the Transactions and Code Sets rule; the Modifications to Electronic Data Transaction Standards and Code Sets rule (68 FR 8381), published in the **Federal Register** on February 20, 2003 (hereinafter the Modifications rule); Standards for Privacy of Individually Identifiable Health Information (65 FR 82462), published in the **Federal Register** on December 28, 2000; Standards for Privacy of Individually Identifiable Health Information; Final Rule (67 FR 53182) published in the **Federal Register** on August 14, 2002; and the Modifications to the Health Insurance Portability and Accountability Act (HIPAA) Electronic Transaction Standards proposed rule (73 FR 49796), published in the **Federal Register** on August 22, 2008 (hereinafter the August 22, 2008 proposed rule) for further information about electronic data interchange, the statutory background and the regulatory history.

In the August 22, 2008 proposed rule, we included a table that shows the full set of HIPAA transaction standards adopted in the Transactions and Code Sets rule, as we proposed to modify them in the August 22, 2008 proposed rule (73 FR 49744), and adopt in this final rule. The list is reproduced here in Table 1:

TABLE 1—HIPAA STANDARD AND TRANSACTIONS

| Standard | Transaction |
|---|---|
| ASC X12 837 D | Health care claims—Dental. |
| ASC X12 837 P | Health care claims—Professional. |
| ASC X12 837 I | Health care claims—Institutional. |
| NCPDP D.0 | Health care claims—Retail pharmacy drug. |
| ASC X12 837 P and NCPDP D.0 | Health care claims—Retail pharmacy supplies and professional services. |
| NCPDP D.0 | Coordination of Benefits—Retail pharmacy drug. |
| ASC X12 837 D | Coordination of Benefits—Dental. |
| ASC X12 837 P | Coordination of Benefits—Professional. |
| ASC X12 837 I | Coordination of Benefits—Institutional. |
| ASC X12 270/271 | Eligibility for a health plan (request and response)—dental, professional and institutional. |

TABLE 1—HIPAA STANDARD AND TRANSACTIONS—Continued

| Standard | Transaction |
|---|---|
| NCPDP D.0 | Eligibility for a health plan (request and response)—Retail pharmacy drugs. |
| ASC X12 276/277 | Health care claim status (request and response). |
| ASC X12 834 | Enrollment and disenrollment in a health plan. |
| ASC X12 835 | Health care payment and remittance advice. |
| ASC X12 820 | Health plan premium payment. |
| ASC X12 278 | Referral certification and authorization (request and response). |
| NCPDP D.0 | Referral certification and authorization (request and response)—Retail pharmacy drugs. |
| NCPDP 5.1 and NCPDP D.0 | Retail pharmacy drug claims (telecommunication and batch standards). |
| NCPDP 3.0 | Medicaid pharmacy subrogation (batch standard). |

## II. Provisions of the Proposed Regulations and Responses to Comments

On August 22, 2008 we proposed to adopt updated standards for the eight adopted electronic transactions standards. We proposed to revise § 162.1102, § 162.1202, § 162.1302, § 162.1402, § 162.1502, § 162.1602, § 162.1702, and § 162.1802 to adopt the ASC X12 Technical Reports Type 3 (TR3), Version 005010 (hereinafter referred to as Version 5010) as a modification of the current X12 Version 4010 standards (hereinafter referred to as Version 4010/4010A) for the HIPAA transactions. In some cases, the Technical Reports Type 3 have been modified by Type 1 Errata, and these Errata were also included in our proposal. The full discussion of our proposal to revise each of the above-referenced provisions can be found in the August 22, 2008 proposed rule (73 FR 49745–49750).

We proposed to revise § 162.1102, § 162.1202, § 162.1302, and § 162.1802 by adding new paragraphs (c)(1) to each of those sections to adopt the NCPDP Telecommunication Standard Implementation Guide, Version D, Release 0 (Version D.0) and equivalent NCPDP Batch Standard Implementation Guide, Version 1, Release 2 (Version 1.2) (hereinafter collectively referred to as Version D.0) in place of the NCPDP Telecommunication Standard Implementation Guide, Version 5, Release 1 and equivalent NCPDP Batch Standard Implementation Guide, Version 1, Release 1 (hereinafter collectively referred to as Version 5.1), for the following retail pharmacy drug transactions: Health care claims or equivalent encounter information; eligibility for a health plan; referral certification and authorization; and coordination of benefits. The full discussion of our proposal to revise each of the above-referenced provisions can be found in the August 22, 2008 proposed rule (73 FR 49751).

We proposed to add a new subpart S to 45 CFR part 162 to adopt a standard for the subrogation of pharmacy claims paid by Medicaid. The transaction is the Medicaid pharmacy subrogation transaction, defined at proposed § 162.1901, and the new standard is the NCPDP Batch Standard Medicaid Subrogation Implementation Guide, Version 3, Release 0 (Version 3.0), July 2007 (hereinafter referred to as Version 3.0) at proposed § 162.1902. The standard would be applicable to Medicaid agencies in their role as health plans, as well as to other health plans that are covered entities under HIPAA, but not to providers because this transaction is not utilized by them. For a complete discussion of the Medicaid pharmacy subrogation transaction and the proposed adoption of Version 3.0, see the August 22, 2008 proposed rule (73 FR 49751–49752).

We proposed to revise § 162.1102 to adopt both Version D.0 and the 837 Health Care Claim: Professional ASC X12 Technical Report Type 3 for billing retail pharmacy supplies and professional services. We proposed that the use of either standard would be determined by trading partner agreements. The full discussion of the proposed change can be found in the August 22, 2008 proposed rule (73 FR 49752–49754).

We proposed to revise the descriptions of the transactions at § 162.1301, § 162.1401, and § 162.1501 to more clearly specify the senders and receivers of those transactions. See the August 22, 2008 proposed rule for a full discussion of this proposal (73 FR 49754). For Versions 5010 and D.0, we proposed a compliance date of April 1, 2010 for all covered entities. For Version 3.0, we proposed a compliance date 24 months after the effective date of the final rule, except for small health plans, which would have to be in compliance 36 months after the effective date of the final rule. Finally, we proposed to revise § 162.923 to resolve the problem of different compliance dates for different entities, such that the requirement for covered entities to use the standards applies only when the covered entity conducts transactions with another entity that is also required to comply with the transaction standards.

In response to the August 22, 2008 proposed rule, we received 192 timely public comments from all segments of the health care industry, including providers, physician practices, hospitals, pharmacies, other health care professionals, health plans, clearinghouses, vendors, standards development organizations, professional associations, consultants, and State and Federal government agencies. We reviewed each submission, and grouped similar or related comments together to address in this final rule, which also enabled us to identify the areas of the proposed rule that required review in terms of policy, consistency or clarity.

In the following sections, we present comments and responses generally in the order in which the topics were presented in the August 22, 2008 proposed rule. There were a number of comments on topics that were not addressed in the proposed rule, and our responses to those comments are provided at the end of this section. Some comments we considered out of scope of the August 22, 2008 proposed rule, and we list several of them at the end of this section as well.

### *A. Adoption of X12 Version 5010 Technical Reports Type 3 for HIPAA Transactions*

In the August 22, 2008 proposed rule, we proposed to revise § 162.1102, § 162.1202, § 162.1302, § 162.1402, § 162.1502, § 162.1602, § 162.1702, and § 162.1802 to adopt Version 5010. In some cases, the version was modified by Type 1 Errata, and these Errata were also proposed for adoption. In general, deficiencies inherent in the current standards continue to cause industry-wide difficulties to such a degree that much of the industry rely on ''companion guides'' and proprietary ''work-arounds.'' The four types of changes in Version 5010 are structural, front matter, technical improvements

and data content changes. The complete discussion of this proposal can be found in the August 22, 2008 proposed rule (73 FR 49745–49749).

*Comment:* Commenters overwhelmingly supported our proposal to adopt Version 5010 because of the technical and business improvements made to the standards. With respect to the specific changes made to Version 5010, commenters expressed their appreciation for the tightened, clear situational rules which will reduce analysis time for everyone, and minimize the need for companion guides. Commenters said that the improved eligibility responses and better search options will improve efficiency for providers and reduce phone calls for both providers and health plans. Commenters also said that the detailed clarifications of commonly misunderstood areas such as corrections and reversals, refund processing, and recoupments should result in a consistent implementation of the X12 835 (remittance advice), which is not the case today. They noted that incorrect implementations of the X12 835 have prevented providers from implementing electronic posting, or automating the data entry of reimbursement information, as widely as they might otherwise. Correct implementation of the X12 835 will reduce phone calls to health plans, reduce appeals due to incomplete information, eliminate unnecessary customer support, and reduce the cost of sending and processing paper remittance advices. Commenters also noted that the greatly improved X12 278 for referrals and authorizations could encourage wider implementation and save labor costs. Commenters noted that the new claims transaction standard contained in Version 5010 significantly improves the reporting of clinical data, enabling the reporting of ICD–10–CM diagnosis codes and ICD–10–PCS procedure codes, and distinguishes between principal diagnosis, admitting diagnosis, external cause of injury and patient reason for visit codes. Commenters noted that these distinctions will improve the understanding of clinical data and enable better monitoring of mortality rates for certain illnesses, outcomes for specific treatment options, and hospital length of stay for certain conditions, as well as the clinical reasons for why the patient sought hospital care. Commenters also noted that another improvement in the updated claims standard is the ability to handle identification of the ''Present on Admission'' (POA) indicator to the diagnoses.

*Response:* We appreciate the overwhelming support of commenters for the adoption of Version 5010.

*Comment:* We received a few comments urging X12 to publish an all-inclusive list of changes made to the standards. Commenters said that a change log is issued after each year's changes are approved. Since Version 5010 incorporates multiple years of changes, users would be required to consolidate multiple change logs. A cumulative change log that includes changes from each interim year should be provided so that all of the changes are contained in one document.

*Response:* We agree that it would be helpful to have a comprehensive list of the changes made to a current version of the standards, and that it would make it easier for covered entities to identify all of the changes that have occurred since the last version of the standard was adopted. We have made this recommendation to the X12 work group as well as the Designated Standards Maintenance Organizations (DSMO).

Many commenters submitted technical comments relating to Version 5010. The comments included highly technical issues and suggested structural changes to the standards, definitional issues requiring clarification, and interpretational issues regarding routine usage of the standards. In total, there were over 470 technical comments. We provided all of the technical comments to X12, which had convened a committee of subject matter experts to review the technical comments and provide us with technical input. The workgroup reviewed each comment and categorized them into several groups as follows: (1) The committee agrees with the comment and the change will be made in the next version of the TR3s (212 comments); (2) the committee does not agree with the comment and believes that a change is not appropriate (156 comments); (3) the functionality already exists elsewhere in the TR3s; commenter requires explanation and references (5 comments); and (4) the comment is a request for interpretation and/or training, and not a request for a change in the TR3s (43 comments). There were 29 comments that were not requests for action, but rather statements of opinion about Version 5010. Of the 212 comments falling into the first category, most were clarifications that would improve usability of the TR3s, but would not adversely affect business processes. Therefore, we will not request that X12 accommodate these changes in Version 5010, but rather would address them in the course of developing later versions of the standards.

After publication of the final rule, all of the technical comments reviewed by the X12 workgroup, with the dispositions, will be posted on the CMS Web site at *http://www.cms.hhs.gov,* in the Regulations and Guidance section, as well as on the X12 portal at *http://www.x12.org.* Where education and/or additional communication are needed about the functionality of the transactions, X12 will provide that in future programs, in collaboration with appropriate industry groups. These Standards Development Organizations (SDO)-sponsored efforts will specifically address the third category of comments in which the committee stated that the functionality exists elsewhere in the TR3s, or the fourth category of comments where the commenter specifically requested additional interpretation guidance.

During the comment review process, X12 provided input to HHS, and we selected several comments to include in this final rule as examples of the types of technical issues that were submitted during the public comment period. In general, suggested corrections, clarifications, and definitional changes to Version 5010 transaction standards will be reserved for future versions of the standards. Any suggested changes to the structure of the standard will need to be evaluated through the standards development process and considered for future versions of the standard. All comments submitted during the comment period for the August 22, 2008 proposed rule will automatically be included in the X12 process for considering change requests. Submitters will not need to re-submit those comments.

*Comment:* We received a few comments requesting clarification of a statement in the August 22, 2008 proposed rule regarding the field size issue in Version 4010/4010A to accommodate ICD–10. In the August 22, 2008 proposed rule, we said that Version 4010/4010A does not provide a means for identifying ICD–10 procedure or diagnosis codes on an institutional claim, and that Version 5010 anticipates the eventual use of ICD–10 procedure and diagnosis codes by adding a qualifier as well as the space needed to report the number of characters that would permit reporting of ICD–10 procedure and diagnosis codes on institutional health care claims. Commenters pointed out that the more accurate explanation for why Version 4010/4010A cannot accommodate ICD–10 is because of the lack of a qualifier

or indicator for the code set name rather than the size of the field for the codes.

*Response:* We note the correction.

*Comment:* One commenter recommended a correction to Version 5010, specific to the claims transactions, to enable it to support the creation of a proposed National Joint Replacement Registry.

*Response:* Because of the technical nature of this comment, we consulted with the X12 work group to better understand the context of the comment and the stated concern. Based on our current understanding of the comment, we agreed with the X12 workgroup on this recommendation for the next version of its TR3s, once the registry is finalized. This means that Version 5010 will not have changes made to it for this purpose at this time, but that the next version of the standards will likely have addressed and resolved this issue.

*Comment:* We received several comments regarding the external code sets used in the standards, such as claims adjustment reason codes. Several commenters wrote about the X12 835 remittance advice code mapping requirements, stating that providers continue to struggle with implementation of the X12 835 as many health plans struggle to provide quality mapping from proprietary to standard codes in the health care payment and remittance advice transaction. Commenters requested that guidelines for mapping be provided.

*Response:* During our consideration of these comments, which we believe apply to the technical standards maintenance process, and which we feel are outside of the scope of this rule, we consulted with the WEDI 835 special work group (SWG) to confirm that the stated concerns were being addressed in its standards revision process. The WEDI 835 SWG indicated that it is developing a recommended set of mapping instructions and information for the industry. In addition, the WEDI 835 SWG has adopted recommendations that will assist in facilitating a more standard implementation of the X12 835.

*Comment:* We received a comment from a large specialty association representing anesthesiology. This group responded to a discussion in the August 22, 2008 proposed rule in which we indicate that efficiencies are gained by allowing only the reporting of minutes for anesthesia time in Version 5010, whereas Version 4010/4010A allows for reporting of anesthesia time in either units or minutes. The commenter stated that this change to Version 5010 will not add efficiency and/or cost savings to the submission and processing of claims for anesthesia care, and requested that units continue to be permitted, or alternatively, that additional time be allowed to implement this change because of its impact on business processes and contracts.

*Response:* Due to the nature of this comment, which addresses potential efficiencies resulting from a technical provision in the Version 5010 implementation guide, we consulted with the X12 workgroup. Based on our discussion with the X12 workgroup, we think that the appropriate course for the commenter to follow would be to submit a change request to the workgroup because the X12 development cycle is ongoing, and change requests will continue to be accepted and reviewed for consideration for the next version of the standards. Given the change in this final rule in the compliance date for Version 5010, we believe the commenter's request for more time to implement the data requirement is addressed.

*Comment:* Several commenters suggested changes to the situational rule for the health care diagnosis codes segment on the X12 837D for dental claims. The situational rule requires inclusion of diagnosis codes only under circumstances involving oral surgery or anesthesia. Commenters suggested that today's dental health plans are offering benefit plans that provide additional coverage for dental services when certain medical conditions exist. The commenter suggested that the situational rule be expanded to allow for dental providers to include diagnosis codes in cases where specific dental procedures may minimize the risks associated with the connection between the patient's oral and systemic health conditions.

*Response:* We do not feel that these comments are within the scope of the proposed rule, but instead pertain to certain technical aspects of the X12 Technical Reports. As such, we shared the comments with the X12 expert committee, which agreed with this recommendation and committed to incorporating this change into future versions of X12 Technical Reports Type 3. As stated earlier, X12 will provide guidance on how to accommodate the functionality in Version 5010.

*Comment:* A few comments focused on the ability of dental providers to report tooth numbers on the X12 837P claim. According to commenters, there is a need for all dental providers to be able to report tooth numbers on medical claims. There were two specific issues raised in this regard. First, even though a field for the tooth number has been designated temporarily, to accommodate claims from oral surgeons and other practitioners, a permanent data element is needed. The second issue pertains to the use of either a national or international tooth numbering system. These commenters stated that both numbering systems should be accommodated in the X12 837 Dental and Professional Guides. Currently, only the Universal National Tooth Designation System is accommodated in Version 5010.

*Response:* Once again, we believe these comments pertain more directly to the technical provisions of the relevant implementation guides. We therefore consulted with the X12 expert committee, which agreed with the first issue regarding the ability of dental providers to report tooth number beyond oral surgery, and committed to allowing this level of reporting in future versions of the X12 standards. Regarding the issue of which tooth numbering system should be accommodated in Version 5010, the X12 committee encourages the commenters to initiate the discussion through the DSMO process with additional business justification for future consideration. The X12 portal has several HIPAA Implementation Guide Requests (HIRs) available which explain how to use the claims transaction for dental services in the interim (*http://www.X12.org*).

Overall, the technical comments received on Version 5010 did not represent issues that would prevent this version of the standard from being adopted as currently proposed. However, enhancements will either be implemented in future versions or further vetted for inclusion in future versions.

*B. Adoption of NCPDP Telecommunication Standard Implementation Guide Version D Release 0 (D.0) and Equivalent Batch Standard Implementation Guide, Version 1, Release 2 (1.2) for Retail Pharmacy Transactions*

We proposed to revise § 162.1102, § 162.1202, § 162.1302, and § 162.1802 by adding new paragraphs (c)(1) to each of those sections to adopt the NCPDP Telecommunication Standard Implementation Guide, Version D, Release 0 (Version D.0) and equivalent NCPDP Batch Standard Implementation Guide, Version 1, Release 2 (Version 1.2) in place of the NCPDP Telecommunication Standard Implementation Guide, Version 5, Release 1 (Version 5.1) and equivalent NCPDP Batch Standard Implementation Guide, Version 1, Release 1 (Version 1.1), for the following retail pharmacy drug transactions: health care claims or

equivalent encounter information; eligibility for a health plan; referral certification and authorization; and coordination of benefits.

Since the time that Version 5.1 was adopted as a transaction standard in the Transactions and Code Sets rule, the industry has submitted requests for modifications to Version 5.1 to NCPDP. Some of these modification requests were necessary for reasons similar to those for the X12 standards—changing business needs—many of which were necessitated by the requirements of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA). The complete discussion of our proposal and reasons for the proposal can be found in the August 22, 2008 proposed rule (73 FR 49751).

*Comment:* Commenters unanimously supported the adoption of Version D.0, agreeing that Version D.0 is needed so that transactions for the Medicare Part D pharmacy benefit can be conducted. We did not receive any technical comments on Version D.0.

*Response:* We agree that Version D.0 is needed to enhance retail pharmacy transactions, as well as to better support Medicare Part D requirements. We are adopting Version D.0 as proposed.

*C. Adoption of a Standard for Medicaid Pharmacy Subrogation: NCPDP Medicaid Subrogation Implementation Guide, Version 3.0 for Pharmacy Claims*

We proposed adding a new subpart S to 45 CFR part 162 to adopt a standard for the subrogation of pharmacy claims paid by Medicaid. We proposed that the transaction would be the Medicaid pharmacy subrogation transaction, defined at proposed § 162.1901, and that the standard for that transaction would be the NCPDP Batch Standard Medicaid Subrogation Implementation Guide, Version 3, Release 0 (Version 3.0), July 2007 (hereinafter referred to as Version 3.0) at proposed § 162.1902. The complete discussion of our proposal and reasons for the proposal can be found in the August 22, 2008 proposed rule (73 FR 49751–49752).

*Comment:* Commenters unanimously supported the adoption of Version 3.0 for Medicaid pharmacy subrogation, and we did not receive any comments in opposition. We also did not receive any technical comments on Version 3.0.

*Response:* We are adopting Version 3.0 as the HIPAA standard at § 162.1902, for the Medicaid pharmacy subrogation transaction, as described at § 162.1901.

*Comment:* Several commenters requested that standards for Medicaid subrogation also be adopted for other claims types in addition to pharmacy claims. The commenters pointed out that the ASC X12 837 claim standards used for processing institutional, professional and dental claims already include the ability to perform Medicaid subrogation and that these standards have also gone through the DSMO approval process.

*Response:* We appreciate the suggestion that we adopt standards for conducting Medicaid subrogation for both pharmacy and medical claims. However, since we did not propose the adoption of Version 5010 for Medicaid subrogation of non-pharmacy claims, we cannot adopt it in this final rule. HHS will consider whether to adopt the X12 standard for non-pharmacy Medicaid subrogation transactions. If we pursue that option, we would propose it in an NPRM and take industry comments into consideration before we would adopt a standard.

We note that, although we are not adopting a standard for Medicaid subrogation for non-pharmacy related claims in this rule, those standards are available for use. Covered entities are not prohibited from using Version 5010 for non-pharmacy Medicaid subrogation transactions between willing trading partners. Some Medicaid agencies have already been successfully using this approach with commercial health plans.

*Comment:* We received comments recommending that HHS clarify that State Medicaid agencies would not be prohibited from continuing to bill using paper claims when necessary.

*Response:* We recognize that there may be situations where it is not cost-effective for State Medicaid agencies and certain plans to use an electronic format for pharmacy claims. For example, while a particular plan may process a large volume of claims, the same plan may have only a small number of Medicaid pharmacy subrogation claims. In addition, States continue to make advancements in identifying other liable payers. This enables States to avoid payment by returning claims to providers and instructing them to bill the other payers. This will result in a decrease in the volume of subrogation claims for Medicaid. Health plans do not always have to conduct electronic transactions for which a standard has been adopted, but if they do, the standard must be used. Section 162.923, however, places additional requirements on health plans so that if a covered entity wanted to conduct the transaction electronically with the Medicaid agency, the agency could not refuse to do so. Medicaid agencies could continue to bill on paper as long as both parties to the transaction agree to conduct the paper transaction. However, Medicaid agencies will still be required to have the capacity to transmit and receive the Medicaid pharmacy subrogation transaction electronically, in standard format, which the Medicaid agency could choose to do through its own system or through a health care clearinghouse.

*Comment:* We received a comment from a pharmacy that supports the adoption of Version 3.0. The pharmacy requested that HHS enforce the use of the standard and eliminate the practice used by some States of recouping money from the pharmacy instead of the third party, which puts additional burden on the pharmacy to bill the third party and in some instances re-bill Medicaid.

*Response:* It is not in the purview of this regulation to eliminate the practice of recoupment from providers. The adoption of the Medicaid pharmacy subrogation standard will not restrict States that choose to recoup from providers in lieu of seeking reimbursement from the third party directly. Once a claim is paid to a pharmacy, the State has the option to seek recovery directly from liable third party payers, or to seek recovery as an overpayment from the provider. We believe that the adoption of the Medicaid pharmacy subrogation standard will greatly improve the efficiency and effectiveness of the health care system which should result in more direct billing of third parties in States that routinely recoup from providers.

*D. Adoption of the NCPDP Telecommunication Standard Implementation Guide Version D Release 0 (D.0) and the Health Care Claim: Professional ASC X12 Technical Report Type 3 for Billing Retail Pharmacy Supplies and Services*

We proposed to revise § 162.1102 to adopt both Version D.0 and the 837 Health Care Claim: Professional ASC X12 Technical Report Type 3 for billing retail pharmacy supplies and professional services. The use of either standard would be determined by trading partner agreements. The complete discussion of our proposal and the reasons for the proposal can be found in the August 22, 2008 proposed rule (73 FR 49752–49754).

*Comment:* We received several comments in support of the proposal to allow the use of either standard for this purpose. Commenters agreed that the NCPDP Telecommunication and Batch Standard supports the billing of the various code sets needed to bill retail pharmacy supplies and professional services (for example, Medication Therapy Management (MTM), vaccine

administration), and that they can use this NCPDP standard for most of their transactions. The commenters said that workflow will be less disrupted when pharmacies can bill for services and supplies using the same NCPDP standard as that used for pharmacy drug claims. Commenters said that the ability to use the NCPDP standard will improve customer service and lower administrative costs. These commenters said that in some cases the X12 standard was appropriate, and that they preferred to have the option of using it on a case-by-case basis.

*Response:* We are adopting our proposal to allow the use of either Version D.0 or Version 5010 for billing retail pharmacy supplies and professional services.

*Comment:* A few commenters noted their support of the proposal, particularly as it relates to improving interoperability of claims processing and adjudication, and suggested that we clarify how our proposal would be implemented with respect to trading partner agreements. Another commenter was cautiously supportive, and said that it agreed with the use of either standard, but that we should emphasize the requirement that trading partner agreements be voluntary, and that a health plan could not create a mandate to use one standard over the other.

*Response:* We reiterate that, by adopting both standards for the one transaction, we are supporting current industry practices with respect to the use of these standards for billing supplies and services that are commonly dispensed or conducted via the retail pharmacy channel. With the exception of the requirements set forth in § 162.915, regarding certain particulars that may not be included in trading partner agreements, we do not dictate the terms of trading partner agreements but expect that health plans and providers will continue to collaborate on the processes for these claim types.

In addition to revising the regulation text at § 162.1102 to allow for the use of either the X12 or the NCPDP standard for billing retail pharmacy supplies and professional services, we are also making a conforming change to the definition of ''standard transaction'' at § 162.103. We indicate that a standard transaction means a transaction that complies with ''an'' applicable standard adopted under this part, rather than ''the'' applicable standard adopted under this part.

*Comment:* One commenter said that if we are adopting standards for retail pharmacy supplies and services, that we should clearly state that both adopted standards apply to Medication Therapy Management (MTM) services. The commenter stated that MTM is a service designed to ensure that Part D drugs prescribed to targeted beneficiaries are appropriately used to optimize therapeutic outcomes through improved medication.

*Response:* In the August 22, 2008 proposed rule, we address MTM services, noting that the MMA provides coverage for MTM, which is a distinct set of services that encompasses a broad range of professional activities and responsibilities. We noted that some pharmacies believe it is appropriate to use the NCPDP standard for MTM services because the services are part of the prescription. Other industry segments, however, believe it is appropriate to use the X12 standard for billing MTM services because they interpret ''professional services'' to require the use of a professional claim (837P) (73 FR 49753). We agree with the commenter and affirm that MTM is included as a service to which both standards apply.

*E. Modifications to the Descriptions of Transactions*

We proposed to revise the descriptions of the transactions at § 162.1301, § 162.1401, and § 162.1501 to clearly specify the senders and receivers of those transactions. We proposed to revise the descriptions for the following transactions: (1) Enrollment and Disenrollment in a Health Plan; (2) Referral Certification and Authorization; and (3) Health Care Claim Status.

*Comment:* The majority of commenters expressed their support for the revised transaction descriptions.

*Response:* We are adopting the revisions to the regulation text as proposed.

*Comment:* Several pharmacies and a national pharmacy chain noted that real-time pharmacy claim transaction statuses are given using the NCPDP standard in real time, whereas Version 4010/4010A is a batch standard. A commenter requested that our definition of the health care claim status transaction specify that Version 5010 (ASC X12 276/277) is used to provide status on X12 transactions for medical claims only, because the commenter wanted clear differentiation between pharmacy and non-pharmacy claims.

*Response:* We are not making a change in our regulation text because we do not think it is appropriate. In § 162.1401, the description of the health care claim status transaction only describes the actions and specifies the senders and receivers of the transaction, whereas § 162.1402 clearly identifies the standard that is adopted for the function described in § 162.1401.

*Comment:* We received a comment requesting a technical clarification to the enrollment and disenrollment in a health plan transaction (§ 162.1501). The commenter stated that there has always been a concern as to when the enrollment/disenrollment (834) transaction was required. This commenter believed that the definition of a group health plan could be applied to the plan sponsor role of a self-funded employer group, which would require the plan sponsor to use the enrollment transaction. The commenter recommended that the final rule include wording to further clarify this requirement, by adding to § 162.1501 the following: For the purpose of enrollment and disenrollment in their health plan, the term sponsor shall include self-funded employer groups that transmit electronic information to their Third Party Administrator (TPA) to establish or terminate insurance coverage for their member.

*Response:* We proposed to describe this transaction as being ''the transmission of subscriber enrollment information from the sponsor of the insurance coverage, benefits, or policy, to a health plan to establish or terminate insurance coverage.'' We provided in the August 22, 2008 proposed rule that a sponsor is an employer that provides benefits to its employees, members, or beneficiaries through contracted services. We further noted that numerous entity types act as sponsors in providing benefits, including, for example, unions, government agencies, and associations (73 FR 49754). We do not think it is appropriate to further revise the definition of the enrollment and disenrollment in a health plan transaction to specify that a sponsor includes any one particular type of entity, as the commenter suggests. We reiterate here that it is not mandatory for a sponsor that is not otherwise a covered entity to use the transaction standard because, as a non-covered entity, HIPAA does not apply to it.

*F. Compliance and Effective Dates*

Versions 5010 and D.0: We proposed to adopt a date of April 1, 2010 for all covered entities to be in compliance with Versions 5010 and D.0. In the August 22, 2008 proposed rule, we discussed our reasons for proposing the compliance timeframe we did. We justified the proposed date based on assumptions that the industry had sufficient expertise in using the X12 and NCPDP standards, and that the system and business changes could therefore be

efficiently coordinated, requiring less time than the original standards for implementation. We also discussed at length an alternative we considered, but did not propose—a staggered compliance timeframe for Versions 5010 and D.0 (72 FR 49754–49757). We received more than 100 comments on compliance dates, with virtually all indicating that the proposed compliance date was not feasible given the extensive changes in Versions 5010 and D.0 from the current standards, and the need for a coordinated implementation and testing schedule. As stated at the beginning of the preamble, this rule is effective March 17, 2009. We note that the effective date is the date that the policies set forth in this final rule take effect, and new policies are considered to be officially adopted. The compliance dates, which are different than the effective dates, are the dates on which entities are required to have implemented the policies adopted in this rule. The compliance dates we now adopt for this regulation are as follows:

- Versions 5010 and D.0—January 1, 2012.
- Version 3.0 for all covered entities except small health plans—January 1, 2012.
- Version 3.0 for small health plans—January 1, 2013.

*Comment:* The majority of commenters opposed the proposed compliance date for Versions 5010 and D.0 and requested additional time for implementation. Most commenters stated that the proposed date did not provide sufficient time to adequately execute a gap analysis for all of the transactions, build programs, train staff, and conduct outreach and testing with trading partners. These commenters stressed the need to avoid compliance extensions or contingency periods because they complicate implementations and increase costs. Health plans and providers expressed concern that the proposed compliance date was unrealistic because large segments of the industry have not been able to meet any of the deadlines for the HIPAA standards to date, including Medicare and many State Medicaid agencies.

The majority of commenters who opposed the April 2010 compliance date suggested a thirty-six month compliance period instead. These commenters said that this amount of time is needed for full implementation because the same programmers, developers and operations staff who must re-design technical and business infrastructure activities to accommodate Versions 5010 and D.0 will also be needed to do similar work to implement ICD–10. In fact, some commenters suggested that the impact of ICD–10 is so significant, that there might not be sufficient industry resources to address Versions 5010 and D.0 because of competing resource needs. A number of health plans stated that, based on their own impact assessments, not only would record layouts and mapping changes be required, but also changes to edits, business procedures and system capabilities. They stated that there are nearly 850 changes between Version 4010/4010A and Version 5010 to be analyzed and potentially implemented. One example is the X12 270/271 eligibility transaction, which will require a more detailed response with less information supplied. Plans will have to determine where the data can be accessed and whether it exists within the current software; in many cases, it will not be a case of moving a few extra fields, and databases may have to be modified or created. These commenters said the complexity of the Technical Reports Type 3 requires in-depth analysis, which will have to be conducted through formal procedures (impact analysis, requirements definition) before design, build, and testing can take place. Similar comments were received regarding the compliance date for Version D.0.

All entities that submitted comments agreed with the proposed adoption of that standard, but did not think enough time was given for implementation. Commenters stated that the transition from Version 5.1 to Version D.0 has functional complexity that will require standardization of practices, new fields, new situational rules for each data element, as well as education, testing and training. These commenters pointed out that, although there have been 22 version releases of the NCPDP standard since Version 5.1, the majority of the industry was reluctant to develop software for any version that was not adopted under HIPAA. These commenters suggested a 36-month implementation schedule for Version D.0.

*Response:* Based on the comments and our analysis of those comments, we are adopting a compliance date later than the date we proposed for all covered entities for Version 5010 and Version D.0. We are requiring that all covered entities be in compliance with Versions 5010 and D.0 on January 1, 2012.

We believe that it is crucial for covered entities to meet certain milestones during the compliance period in order to ensure full, successful, and timely compliance. The NCVHS recommended a framework for compliance that we believe will be very effective for these purposes. Therefore, we describe below the NCVHS recommendation and the schedule to which we expect covered entities to adhere during the compliance period.

A letter from the NCVHS to Secretary of HHS Michael Leavitt dated September 26, 2007 (*http://www.ncvhs.hhs.gov*) summarized the Committee's Standards and Security Subcommittee's HIPAA transaction hearings of July 2007, noting that ''the timing of standards implementation is critical to success.'' The NCVHS weighed the industry testimony presented at that hearing and noted that HHS should consider establishing two different levels of compliance for the implementation of Version 5010. Level 1 compliance, as interpreted by the NCVHS, means that the HIPAA covered entity could demonstrate that it could create and receive Version 5010 compliant transactions. Level 2 compliance was interpreted by the NCVHS to mean that HIPAA covered entities had completed end-to-end testing with all of their partners and were ready to move into full production with the new version. The NCVHS letter stated that: ''it is critical that the industry is afforded the opportunity to test and verify Version 5010 up to two years prior to the adoption of Version 5010.'' The letter's Recommendation 2.2 states that ''HHS should take under consideration testifier feedback indicating that for Version 5010, two years will be needed to achieve Level 1 compliance.''

Accordingly, our expectations are as follows. The Level 1 testing period is the period during which covered entities perform all of their internal readiness activities in preparation for testing the new versions of the standards with their trading partners. When we refer to compliance with Level 1, we mean that a covered entity can demonstrably create and receive compliant transactions, resulting from the completion of all design/build activities and internal testing. When a covered entity has attained Level 1 compliance, it has completed all internal readiness activities and is fully prepared to initiate testing of the new versions in a test or production environment, pursuant to its standard protocols for testing and implementing new software or data exchanges. The Level 2 testing period is the period during which covered entities are preparing to reach full production readiness with all trading partners. When a covered entity is in compliance with Level 2, it has completed end-to-end testing with each of its trading

partners, and is able to operate in production mode with the new versions of the standards by the end of that period. By ''production mode,'' we mean that covered entities can successfully exchange (accept and/or send) standard transactions and as appropriate, be able to process them successfully.

During the Level 1 and Level 2 testing periods, either version of the standards may be used in production mode—Version 4010/4010A and/or Version 5010, as well as Version 5.1 and/or Version D.0—as agreed to by trading partners. Covered entities should be prepared to meet Level 1 compliance by December 31, 2010, and Level 2 compliance by December 31, 2011. After December 31, 2011, covered entities may not use Versions 4010/4010A and 5.1. On January 1, 2012, all covered entities will have reached Level 2 compliance, and must be fully compliant in using Versions 5010 and D.0 exclusively.

The final compliance date provides an implementation period of 36 months, or three years, as requested by the majority of the commenters. Given this revised implementation period that accommodates NCVHS and industry concerns, we expect that covered entities will be able to meet the compliance date. We anticipate that, since there was support for a phased-in schedule, health plans and clearinghouses will make every effort to be fully compliant on January 1, 2012. Covered entities are urged to begin preparations now, to incorporate effective planning, collaboration and testing in their implementation strategies, and to identify and mitigate any barriers long before the deadline. While we have authorized contingency plans in the past, we do not intend to do so in this case, as such an action would likely adversely impact ICD–10 implementation activities. HIPAA gives us authority to invoke civil money penalties against covered entities who do not comply with the standards, and we have been encouraged by industry to use our authority on a wider scale. We refer readers to the HIPAA Enforcement Final Rule (71 FR 8390), published in the **Federal Register** on February 16, 2006, for our regulations implementing that HIPAA authority.

Compliance Date for Version 3.0

For implementation of Version 3.0 for the Medicaid pharmacy subrogation transaction, we proposed to revise § 162.900 to adopt a compliance date of 24 months after the effective date of the final rule for all covered entities, except for small health plans, which would have 36 months. We also proposed to revise § 162.923, entitled ''Requirements for covered entities'' to make paragraph (a) applicable only to covered entities that conduct transactions with other entities that are required to comply with a transaction standard. We proposed this change in order to address the situation where transactions require the participation of two covered entities, where one entity is under a different set of compliance requirements. We expect that the change we proposed to § 162.923 would resolve the problem of a State Medicaid agency attempting to transmit a transaction using Version 3.0 to a small health plan before the small health plan is required to be compliant and could, therefore, reject the transaction on the basis that it is in the standard format (73 FR 49754–49755).

*Comment:* We received one comment explaining that Version 3.0 had to be implemented either at the same time as Version D.0, or after, because certain data elements present in D.0, but not in Version 5.1, were needed in order to use Version 3.0. The commenter also believed that willing trading partners would be able to agree to use the Medicaid pharmacy subrogation standard voluntarily at any time after the effective date and before the compliance date.

*Response:* We agree that Versions D.0 and 3.0 are tied together by certain data elements necessitating their concomitant or sequential implementation respectively. To accommodate these technical needs, we are making the effective date of Version 3.0 later than the effective date for the other parts of this rule. We are making the effective date for the portion of the rule concerning the adoption of Version 3.0 January 1, 2010, which means that covered entities, except small health plans, must be in compliance with Version 3.0 no later than January 1, 2012. Small health plans must be in compliance no later than January 1, 2013. This gives States and health plans a two-year planning, implementation and testing window, in contrast to the three years being provided for Versions 5010 and D.0. States and plans are encouraged to do as much planning in the year before the effective date (calendar year 2009) as possible, to take advantage of that window and the work already under way for Version D.0, since Versions D.0 and 3.0 are tied together. In other words, States may use calendar year 2009 to conduct a preliminary analysis of Version 3.0 changes, in concert with their analysis of Version D.0 changes. States should also prepare and submit their budget requests to secure funding for design, development and implementation in 2010 and 2011, which would leave time to conduct testing with trading partners between January 2011 and January 2012.

*Comment:* We received a number of comments from providers and health plans supporting the proposed revision to § 162.923(a).

*Response:* We are adopting the revision to § 162.923(a), as proposed in the August 22, 2008 proposed rule.

Timeline

In the proposed rule, we provided a timeline for implementation and compliance of ICD–10 and Versions 5010 and D.0. We included the timeline to enable the industry to conduct preliminary planning (73 FR 49757), and indicated that the proposed timeline represented our best estimate for industry implementation at the time. We also indicated that the timeline was subject to revision as updated information became available. We provide the revised timeline here.

TIMELINE FOR IMPLEMENTING VERSIONS 5010/D.0, VERSION 3.0 AND ICD–10

| Version 5010/D.0 and Version 3.0 | ICD–10 |
|---|---|
| 01/09: Publish final rule | 01/09: Publish Final Rule. |
| 01/09: Begin Level 1 testing period activities (gap analysis, design, development, internal testing) for Versions 5010 and D.0. | |
| 01/10: Begin internal testing for Versions 5010 and D.0. | |
| 12/10: Achieve Level 1 compliance (Covered entities have completed internal testing and can send and receive compliant transactions) for Versions 5010 and D.0. | |
| 01/11: Begin Level 2 testing period activities (external testing with trading partners and move into production; dual processing mode) for Versions 5010 and D.0. | 01/11: Begin initial compliance activities (gap analysis, design, development, internal testing). |

TIMELINE FOR IMPLEMENTING VERSIONS 5010/D.0, VERSION 3.0 AND ICD–10—Continued

| Version 5010/D.0 and Version 3.0 | ICD–10 |
|---|---|
| 01/12: Achieve Level 2 compliance; Compliance date for all covered entities. This is also the compliance date for Version 3.0 for all covered entities except small health plans *.<br>01/13: Compliance date for Version 3.0 for small health plans. | 10/13: Compliance date for all covered entities (subject to the final compliance date in any rule published for the adoption of ICD–10). |

* Note: Level 1 and Level 2 compliance requirements only apply to Versions 5010 and D.0

Other Comments Pertaining to the Compliance Date Specific to Versions 5010 and D.0

*Comment:* We received a few comments from Medicaid agencies explaining why the compliance dates were problematic from a funding perspective. Commenters explained that the State budget environment requires more lead time to obtain project authority and resources on the scale necessary to implement Versions 5010, D.0, and 3.0. One State said that it could not begin any substantial required documentation activities until there is a final rule. Finally, a number of States said that they are facing fairly significant budget shortages. Commenters said that, even with 90 percent federal matching rates, resource requests based on a proposed rule would be unlikely to receive approval from legislatures.

*Response:* The comments from the States were compelling with respect to funding and planning issues, and were helpful in our reconsideration of the proposed compliance dates. We acknowledge the need to work with States to coordinate their budget requests and implementation activities with legacy system replacement.

*Comment:* Another State agency recommended that the final rule contain a waiver provision to permit covered entities to seek a waiver for implementation of Version 5010 in any existing legacy system that is scheduled for replacement.

*Response:* Waivers cannot be accommodated. Neither the statute nor the regulations provide for waivers for meeting the standards set forth under HIPAA.

*Comment:* A few commenters favored the proposed compliance dates for Versions 5010 and D.0, citing their eagerness to begin benefiting from the updated standards as soon as possible, particularly because it has been so long between adoption of Versions 4010/4010A1 and 5.1, and the updated versions of those standards.

*Response:* We believed the proposed compliance dates were reasonable for the reasons provided in the proposed rule (73 FR 49754–49757). Based on the comments however, we acknowledge that many significant actions would have to take place very quickly (for example, budget requests, hiring and recruitment of subject matter experts, design work, schedule of programming installations, etc.) in order to meet an April 2010 compliance date, and as stated above, have adopted a later date for both standards.

*Comment:* The majority of commenters agreed that small health plans should not have additional time (for example, an additional year as in past regulations) to become compliant with Versions 5010 and D.0 because these entities are, or should be, already using Version 4010/4010A and Version 5.1 through clearinghouses or their own systems. Small health plans should be at the same stage of implementation as any other covered entity, meaning that their organizations, business associates and trading partners are now well-versed in the technology and requirements for using Version 4010/4010A and Version 5.1, and should not require additional time to accommodate the new versions. All covered entities are essentially at the same point with respect to having implemented the standards, identified and resolved business process issues, trained staff, and incorporated the use of standards process into their existing infrastructure.

*Response:* We agree with commenters regarding the compliance dates for small health plans, and are requiring all covered entities, including small health plans, to be in compliance on the same date.

*Comment:* We received several comments supporting a different schedule which involved staggering compliance based on either covered entity type or transaction type over the course of 3 years. In the first scenario, all health plans and clearinghouses would be required to be compliant one year before covered health care providers in order to ensure that providers could begin testing with all trading partners the following year. For example, under a 36-month compliance scenario, health plans and clearinghouses would have to be in compliance 24 months after the effective date, and prepared to conduct testing with trading partners over the next 12 months. We also received a few comments that suggested a staggered implementation schedule by transaction type. For example, the updated standards for health care claims and related transactions could be implemented first, followed by updated standards for eligibility transactions, claims status transactions, etc. However, the majority of commenters who had opinions about a staggered implementation schedule based on transaction type believe that assigning different compliance dates to different transactions would not have the intended effect of ensuring compliance by the deadline, nor would it facilitate the testing process. These commenters explained that the use of certain transactions, particularly auxiliary transactions (for example, authorizations and referrals), is so inconsistent across the industry, there would be no effective means by which to stagger their implementation. The use of the auxiliary transactions is uneven—many entities do not use the claims status transactions because they have on-line access to their billing files; many do not use the eligibility transaction because, historically, it has not provided useful information. Thus, entities actually have very little experience with these transactions, and may continue to use them minimally. They do not wish to expend limited resources on a transaction that will not have a return on investment in the early years.

*Response:* We believe that different compliance dates for different types of covered entities could significantly complicate trading partner testing, particularly for those entities that function as both health plans and health care providers, as well as for other entity types that perform in multiple roles. It is likely that different compliance dates for different entity types could be confusing to the industry, and could actually delay some implementations while entities waited for trading partner compliance. For

example, this approach presumes that providers and their software vendors will be making system and operational changes at the same time as the health plans and clearinghouses in order to be ready for testing.

*Comment:* We received a number of comments about our assumption in the August 22, 2008 proposed rule that staggered implementation dates for health plans and clearinghouses would not be feasible because of robust trading partner tracking systems that might be needed so that entities could know which providers were testing Versions 5010 and/or D.0, which were using Versions 4010/4010A and/or 5.1, and which had fully converted to Versions 5010 and/or D.0. This would be very complicated to build and manage between the thousands of providers, health plans, vendors and clearinghouses. Commenters also expressed concern about the impact on coordination of benefits with secondary health plans, since each health plan would be implementing Version 5010 at different times. One commenter said that the reality is that all covered entities would need robust trading partner tracking systems for any implementation plan, and that coordination of benefits would be disrupted with any implementation plan because not all covered entities would be ready on the same date to send and receive the updated HIPAA standards. Commenters said that covered entities would have to support the dual use of Version 4010/4010A and Version 5010 until the compliance date in any scenario. They explained that all covered entities would need to test at different times during the implementation process, and that a complex scheduling process would need to exist between health plans, clearinghouses and providers testing and migrating to the updated transactions at different times.

*Response:* We agree with the commenters' points regarding the complexity of programming, testing and coordinating all implementation efforts, regardless of the timeline, if we were to adopt a staggered implementation schedule by entity type or transaction type.

*Comment:* Some commenters said that all health plans, including State Medicaid agencies, must be held to the same compliance dates, and that compliance with prior HIPAA implementations varies between non-government health plans and State Medicaid agencies. Since Medicaid agencies have lagged behind and not met implementation deadlines, hospitals and providers have had to maintain a dual submission strategy which incurs significant additional costs to the providers. We received a number of comments expressing particular concern about Medicare mandating full compliance prior to the compliance date adopted by the final rule. The commenters specifically referenced written communication they had received from Medicare stating that it (Medicare) would have an early compliance date for Version 5010 for the coordination of benefits transaction. The commenters stated that, if Medicare requires covered entities to be ready to shift to dual processing several months before the adopted compliance date, there will be significant implementation problems for many providers and other health plans. The commenters also stated that, if Medicare mandates use of Version 5010 for coordination of benefits, before any of the other transactions were mandated for use, other health plans would have to run separate processing systems for just the one transaction. Other commenters stated that health plans do not maintain separate processing systems for each additional health plan with which they conduct COB transactions. Commenters stated that, if Medicare is allowed to mandate early compliance, it would exacerbate an already difficult situation, and reiterated that no entity should be allowed to require their trading partners to implement the standards in a production environment, prior to the HHS compliance date, if the trading partner did not agree. These commenters feel that such a prohibition would help ease the implementation as solutions are deployed across all entities, over a defined period of time.

*Response:* We agree that no covered entity, including State Medicaid agencies or Medicare, should be allowed to require compliance earlier than the compliance date we are adopting in this final rule. If entities were allowed to require earlier compliance, this would cause undue financial and operational burdens on other segments of the industry. For example, one State chose to implement the NPI before the compliance deadline, which caused significant difficulties and expenses for providers because, in some cases, they were not ready to comply, and therefore had to revert to paper. In many cases, the State's other trading partners, namely other commercial health plans and the Federal Medicare program, were not prepared to accept the NPI, which meant that providers (and their vendors and clearinghouses) in that State had to support a complex infrastructure in which the NPI was included on some claims, but not on others. HHS will ensure that appropriate agencies and departments work together to monitor Medicaid implementation work plans, testing and readiness on a regular basis throughout the implementation period.

We are adopting a revision to § 162.925, by adding a new paragraph (a)(6), to specify that a health plan is not permitted to delay, reject, or attempt to adversely affect the other entity or the transaction on the basis that the transaction does not comply with another adopted standard during the period from the effective date of the final rule until the compliance date. With respect to coordination of benefits, this means, for example, that Medicare will not be able to require of trading partners that they be in full compliance with Version 5010 prior to January 1, 2012, unless willing trading partners agree to do so. Health plans that participate in Medicare's Coordination of Benefits program will be able to work with Medicare to arrange a mutually agreeable testing schedule in order to expedite this transaction, but they are not required to do so, and may revert to receiving claims directly from providers if they choose to do so.

*Comment:* Commenters said that a key component of any implementation schedule is testing, and a large number of commenters stressed the importance of both internal testing as well as external testing with trading partners. Many commenters stated that testing often occurs at or near the end of the compliance period, and that such last-minute testing causes scheduling problems and creates uncertainty about whether changes were applied correctly. Commenters said that, in many cases, hospitals and other providers must wait for vendors and health plans to schedule testing. Many commenters said that health plans do not provide sufficient advance communication about their testing efforts or their readiness to implement the standards, and providers have indicated that it is difficult to obtain the name of the individual or department within the health plan with whom they should coordinate. One commenter explained that testing is done in three parts: Testing of the standards themselves for workability; conformance testing of products and applications that send and/or receive the transactions; and end-to-end testing to ensure interoperability among trading partners. All three levels of testing are critical to the successful implementation of Versions 5010, D.0 and 3.0, and efforts to execute all three levels of testing will minimize delays and avoid many of the

complications afflicting previous implementations.

*Response:* We agree that testing is absolutely crucial to resolving problems before the implementation date to ensure that there are no payment delays or service disruptions. In the August 22, 2008 proposed rule, we discussed and emphasized the importance of testing to a successful and timely implementation (73 FR 49755–49756). Based on the industry's experience in previous implementations, it is clear to us that testing is core to resolving issues early and effectively. We have revised the regulation text that identifies the adopted standard for each transaction, in every instance, to enable testing to occur during the period from the effective date of the final rule until the compliance date for Versions 5010 and D.0. Our revised regulations permit the dual use of standards during that timeframe, so that either Version 4010/41010A1 or Version 5010, and either Version 5.1 or Version D.0, may be used for the period prior to the compliance date. We note that the adoption of two standards for one transaction during the period prior to compliance does not mean that covered entities must use both standards, but, rather, that the use of either standard is permitted.

*Comment:* Another commenter said that the importance of vendor compliance cannot be underestimated, as practice management system vendors are critical to provider compliance. Any delays in vendor implementation of compliant products will delay end-to-end testing, so providing sufficient time for the vendors to design, build and test, will only facilitate the process. A large software vendor explained that, to enable compliance with Versions 5010 and D.0, users must continue to use their current software while testing new software updates to accommodate the changes. The commenter explained that there are often several stages of software revisions, and this necessity may add additional time to the development and implementation process. Finally, testing and certification activities on each version must take place to ensure compatibility and stability of software. This process almost always takes longer than expected.

*Response:* While we do not have the authority to regulate vendors, as they are not covered entities, we agree about the critical importance of vendor testing, and that, in particular, accurate, quality software development and testing are critical to the successful implementation of the updated versions. We also agree that appropriate time is necessary for installation, user training and coordination of testing with trading partners. By adopting a later compliance date, we hope to ensure that software development vendors have sufficient time to conduct the appropriate internal and external testing such that the software they provide to their covered entity clients is compliant with the standards, capable of facilitating the transmission and receipt of the new versions of the standards.

*G. Miscellaneous/General Other Comments*

This section includes comments and responses to other issues raised during the public comment period.

Claims Attachments

*Comment:* We received several comments requesting that HHS not adopt standards for electronic health care claims attachments at this time because implementation of Versions 5010, D.0, and 3.0, and ICD–10 would make it impossible to also implement standards for claims attachments. One commenter stressed that, since claims attachments included another new standard—the HL7 Attachment Specifications—the industry would not be able to accommodate the additional work needed to implement the claims attachment standard if Versions 5010, D.0, and 3.0, and ICD–10 also had to be implemented in that same time period.

*Response:* We appreciate and will consider the commenters' concerns for not wanting to have to implement the electronic health care claims attachment standards at the same time as Versions 5010, D.0 and 3.0, and ICD–10.

Standards Adoption and Modifications

In the August 22, 2008 proposed rule, we provided an explanation of the procedures for maintaining existing standards and for adopting new standards and modifications to existing standards (73 FR 49744–49755). That section of the proposed rule describes how § 162.910 sets out the standards maintenance process and defines the role of SDOs and the DSMOs. For additional information about the DSMO process and procedures, refer to the Web site at *http://www.hipaa-dsmo.org/Main.asp*. We also described the process for adopting modifications to standards under § 162.910, which is discussed in detail in the Transactions and Code Sets rule (65 FR 50312), and implemented at § 162.910.

The proposed modifications and the new transaction standards were developed through the process that conforms with § 162.910. We received many technical comments specific to the Version 5010 standards, indicating that there are still opportunities for improvement in that version. We did not receive any technical comments specific to Version D.0.

*Comment:* A few commenters stated that greater industry involvement in the X12 standards development and balloting process would be helpful to their industry segment, e.g., health care providers, hospitals, health plans, health care clearinghouses and vendors.

*Response:* We have suggested to the X12 SDO that it consider the following: (1) Expanding the current outreach efforts to industry to obtain more diverse representation from all covered entity types. This would take place during the development of new versions as well as during the balloting process; and (2) securing industry volunteers to test the balloted standards before they are proposed to NCVHS. That way, when the suggested modifications are submitted to NCVHS for consideration, even greater industry support can be expected.

*Comment:* We received a few comments suggesting that HHS streamline the standards adoption process. Commenters said that the marketplace is evolving at a rapid pace, creating new products, new technologies and new methods of conducting business. They stressed that, even though X12 continues to improve the standards each year, the industry has not had the opportunity to benefit from necessary and helpful changes because too much time elapses between the adoption of versions. Others reiterated that there is a need for the updated standards to be available for use by the industry as they are tested and balloted. For example, one entity found that the industry needs information about tax advantaged payment mechanisms (for example, Medical Savings Accounts, Health Savings Accounts, Health Reimbursement Accounts, etc.) that are now commonly in place to support the movement to consumer-directed health care. Version 5010 does not contain the information needed by patients or providers to determine the financial impacts and flows. Commenters said that the industry cannot wait another eight years to be able to exchange this type of crucial information for critical market needs. They suggest that a more streamlined way to develop, implement and adopt updated standards must be found. Commenters suggested that HHS work with industry stakeholders to identify and implement a way to increase the predictability and timeliness of adopting updated standards, including a means by which the rulemaking process might not be

necessary to allow the industry to use updated versions of the standards.

*Response:* HHS has considered similar concerns in the past, and continues to assess potential alternatives within the context of HIPAA and the Administrative Procedures Act (APA). HHS will continue to work with industry to identify a means by which updated standards can be used on a timelier basis, consistent with the law.

*Comment:* One commenter recommended that HHS adopt the X12 standard transaction formats in the final rule, but not the specific versions of the X12 standards or Technical Reports Type 3 (TR3s). The commenter stated that it has been eight years since publication of the Transactions and Code Sets rule adopting the Version 4010/4010A implementation guides. The long passage of time since the initial adoption has resulted in widespread workarounds in the industry to address Version 4010/4010A's deficiencies. The commenter suggests that HHS could designate the DSMO coordinating committee to biannually determine whether a change makes sense for the industry, and which updated TR3s would be implemented. The DSMO committee would still provide open public access to the standards development process, but this approach would eliminate the time-consuming NPRM steps and enable smaller iterative version updates to take place. The commenter noted that the ongoing maintenance of the adopted code sets is already handled outside of the NPRM process. Under this recommendation, new standards, as opposed to updates or modifications to the standards, would continue to be adopted by HHS utilizing the regulatory process.

*Response:* HHS has evaluated options for streamlining the process of adopting new versions of the standards, and agrees with commenters that alternate, more expedient methods are necessary, consistent with HIPAA and the APA. We are committed to working with industry and the standards organizations to develop a process that can be proposed in the near future, consistent with the law. With respect to the commenter's reference to the ongoing maintenance of the adopted code sets, HHS notes that there is specific statutory authority in HIPAA which permits the routine maintenance, testing, enhancement and expansion of code sets outside of the rulemaking process; modifications to adopted code sets, however, are adopted by means of the rulemaking process.

Outreach, Education and Training

In the proposed rule, at 73 FR 49756, we stated that HHS would begin preparations for, and execution of, outreach and education activities, and the engagement of industry leaders and stakeholder organizations to provide a variety of educational and communication programs for various constituencies.

*Comment:* Many commenters advised HHS to establish a network of training and outreach partners to work collaboratively to educate the industry, and outlined the education and outreach strategies that will be needed. Commenters stated there were needs for: National associations to collaborate on education efforts; a consistent set of messages and/or materials from authoritative sources; recognition that different audiences may need different levels of training; and in-person training to supplement Internet training and printed documents. Several commenters recommended that HHS develop a consistent standard set of training materials for distribution to industry groups as soon as possible. The commenter suggested that key professional associations should be the source for common educational materials. One commenter suggested that HHS collaborate with other organizations to publish a ''lessons learned'' guidance document. A number of commenters recommended that HHS begin outreach activities as quickly as possible, and to clearly differentiate between HHS Policy guidance (for the industry at large) and Medicare guidance (specifically for Medicare providers). Other commenters agreed, indicating that this was important because Medicare policies do not often apply to other covered entities' policies, and information is confusing to providers when it is not clearly differentiated. Another commenter provided a summarized list of requested technical assistance which included migration tools that automatically translate Version 4010/4010A to Version 5010, and Version 5010 to Version 4010/4010A.

*Response:* We agree that it is important that consistent and accurate messages and/or materials be developed by authoritative sources, and will work closely with industry to put together a comprehensive, diverse plan that addresses Medicare-specific policies, as well as industry-wide policies and implementation issues.

We agree that different audiences may need different levels of training. Our current plan is to develop and disseminate high-level materials, and we anticipate that the industry will continue to offer the more in-depth materials that specific stakeholder groups may need. HHS already dedicates a section of its Web site to the HIPAA regulations, including guidance papers, FAQs, and links to external Web sites and to other useful resources. The Web site is *http://www.cms.hhs.gov*.

*Comment:* We received a number of comments suggesting that HHS ensure better coordination of the communication of, by, and between, Medicare and Medicaid.

*Response:* We agree that all segments of the industry should collaborate and communicate on implementation to avoid misunderstanding and to coordinate testing schedules. We will work with State Medicaid agencies to support their development of communication and outreach initiatives as we develop the overarching implementation strategy for education. We will also help to ensure that there are regular opportunities for Medicare and Medicaid to collaborate on implementation strategies.

Companion Guides

In the August 22, 2008 proposed rule, we discussed the deficiencies in Version 4010/4010A and Version 5.1, and the fact that the industry has come to rely upon health plan-specific companion guides to address the ambiguities in the implementation guides for each of the standards (73 FR 49746). It is possible that the reliance on companion guides has minimized some of the potential benefits offered by the standards. Based on testimony from the standards organizations and other industry representatives to NCVHS, the improvements to Version 5010 should minimize dependence on companion guides. Some of those improvements include clarifications of the standard requirements, and consistency in requirements across all of the transactions. In the August 22, 2008 proposed rule, we said that companion guides could potentially be eliminated if the updated versions of the standards were adopted.

*Comment:* We received a number of comments from the industry on this subject, offering support for the elimination of companion guides because of the complexities they create in implementing the standards. Health plans were less supportive of a complete elimination of companion guides, but did, in general, comment that the use of companion guides could be reduced, and that their content could be less complex. A few commenters requested that HHS prohibit the use of companion guides. They justified this

recommendation based on the use of these guides continuing to undermine the potential of standards. A few of the clearinghouse commenters suggested that companion guides be limited to providing supplemental information and instruction, but that they could not be used to mandate the use of certain situational fields. Other commenters felt that the next version of the standard should do away with nearly all situational data elements, and only leave a bare minimum of fields eligible to be situational, thus further reducing the need for companion guides. A few of the commenters who supported the use of companion guides said that these would always be necessary because health plans would always have unique business rules, and that sometimes these rules or practices were to the advantage of the provider.

*Response:* We acknowledge the issues presented by companion guides, but note that we do not have the authority to expressly prohibit the use of these guides. However, based on our review of many such documents, and the ongoing efforts of the industry to collaborate, we strongly discourage health plans from having companion guides unless they are focused significantly on the basics for connectivity, trading partner arrangements, and use of situational data elements. We encourage X12 to evaluate, and address as appropriate, industry comments specific to situational data elements, so that the minimum number of fields remain situational. This will enhance standardization and further reduce the need for companion guides. We also note that we have already published FAQs clarifying that, if companion guides contradict the implementation guides, the transaction will not be compliant. Covered entities may use the existing enforcement process to submit official complaints to HHS. Once an investigation is opened, HHS will review the companion guide at issue and a determination will be made as to its compliance with the standard(s).

Standardization of Data Content

*Comment:* We received a few comments requesting that HHS support the work of some industry groups, such as the Coalition for Affordable and Quality Healthcare (CAQH), that are attempting to standardize the use of data content to maximize the benefits of transaction standards—in other words, some industry representatives are trying to build consensus on the data elements that everyone will request and provide, to make implementation more consistent throughout the industry. A few commenters said that one group has been working on standard content for the eligibility standard, so that the transaction provides more robust and useful information above and beyond what is currently a ''yes/no'' requirement in response to a request for information about an individual's eligibility for health plan benefits. One commenter requested that HHS support the CAQH certification process for the use of the eligibility transaction, in which organizations voluntarily agree to have their programming reviewed and approved by CAQH, and those organizations agree to use all of the same data elements as others who are participating in the certification program.

*Response:* We do support the work of individuals and organizations in efforts to make the standard transactions more useful to the industry as a whole. While HHS cannot mandate participation in any certification programs, we do support any efforts towards improved compliance with the standards, as well as efforts towards maximizing the usefulness and usability of the standards. We also reiterate that we have published FAQs clarifying how a covered entity may file a complaint against another entity who it believes may not be in compliance with the implementation guides.

Definition of Compliance

*Comment:* We received a few comments suggesting that we adopt a definition of the term ''compliance,'' using the text from the TR3 guides, which provides that compliance indicates the receiver of a standard transaction does not have to reject a transaction that is not in compliance with all of the rules within the standard. According to commenters, the TR3 guides have a definition of compliance that states a covered entity is out of compliance if it receives and accepts a transaction that is a non-standard transaction. These commenters believe this statement conflicts with an HHS FAQ which states that a receiver may not accept a non-compliant transaction. The commenter suggests that the sender of the transactions is responsible for the compliance of the transaction, and HHS should not consider the receiver to be out of compliance if it accepts a non-compliant transaction. Another commenter said that HHS should encourage an ''ignore, don't reject'' approach to implementation, which would mean that, if a transaction is submitted conforming to the standard, but it contains more information than is necessary for an entity to process that transaction, the additional information should be ignored by the receiver, and the transaction not rejected.

*Response:* The definitions in the TR3 reports are not specific to the compliance of the transaction with the HIPAA rules, so the way ''compliance'' is defined by the TR3 reports does not apply to compliance under HIPAA. We believe our regulations sufficiently address the requirements for compliance. Our regulations at § 162.923 address the requirements for a covered entity to conduct a standard transaction when it conducts a HIPAA transaction using electronic media, and we define ''standard transaction,'' as revised in this rule, as ''a transaction that complies with an applicable standard adopted under this part.'' Regarding the commenter's suggestion of an ''ignore, don't reject'' policy, we point out that § 162.925(a)(3) provides that a health plan may not reject a standard transaction on the basis that it contains data elements not needed or used by the health plan. Finally, we do have an enforcement program through which covered entities may file complaints, and we continue to encourage the industry to utilize this program when faced with conflicts about the compliance of a transaction.

Pilots

*Comment:* We received a number of comments suggesting that standards should be pilot tested before adoption. These commenters said that pilot testing the standards is needed long before a standard is proposed for adoption because such testing identifies potential pit-falls and could identify and correct unanticipated issues with a particular standard before it is officially adopted. A few commenters noted the lack of a pilot testing process and suggested that HHS, with industry input, define a pilot testing process for future standards. Another commenter recommended that pilot testing proceed in a certain sequence, beginning with internal unit testing, and followed by system testing and integration testing, and ultimately ending with trading partner testing. One commenter stated that, without workability testing, the government, X12 and the industry would be repeating implementation mistakes that were made with Version 4010/4010A. That same commenter recommended that the provisions for permitting exceptions from the requirements to comply with the standards in order to test proposed modifications (§ 162.940) be suspended until the current version of a standard was no longer in use, in other words, that some date certain would be set to ''retire'' or sunset a particular version of a standard. The

commenter said that such a suspension would represent cost and administrative savings to all parties because it would simplify the process of accommodating new versions of the standards. We also received a comment suggesting that HHS fund pilot testing and allow an additional twelve months for the testing before the compliance date of a final rule, implying future final rules. No commenters suggested that Version 5010 be tested prior to adoption; rather, recommendations were for the future review and adoption of new versions of the standards.

*Response:* We recognize the value of pilot testing and its importance in the standards implementation process, and intend to work with the industry to define parameters for pilot testing in the future. We also encourage industry stakeholders and the standards organizations to take the lead for initiating pilot tests and monitoring the success of such tests.

Acknowledgements

Version 5010 accommodates the acknowledgement transaction, for the data receiver to communicate any errors or transmission problems back to the sender. Many health plans and clearinghouses use acknowledgement transactions, and they are free to do so using the standards they choose for that transaction. We did not propose to adopt a standard for the acknowledgement transaction in the proposed rule, so we will not adopt one here.

*Comment:* We received several comments on this subject, with most commenters indicating that acknowledgements improve the process of receiving and correcting an error and resubmitting the correction back to the receiver. These commenters suggested that HHS adopt Version 5010 for the acknowledgement transaction. Commenters said that migration to standard acknowledgement transactions would offer significant business benefits by ensuring that transactions are received and front-end errors reported on a timely and consistent basis. In spite of the support for adopting an acknowledgement transaction standard, commenters also mentioned that they did not wish in any way to delay overall implementation of Version 5010 by waiting until an acknowledgement transaction standard is proposed and adopted. In other words, if the choice was to wait to adopt Version 5010 until the NCVHS advises the Secretary to also adopt Version 5010 as the standard for the acknowledgement transaction, the commenters did not want to see their suggestion go forward.

*Response:* Before we would adopt an acknowledgement transaction standard, such standard would have to have been vetted through the standards adoption process that includes approval of a DSMO change request, recommendation by the DSMOs to the NCVHS, and recommendation by the NCVHS to the Secretary. Even though the chair of the X12 standards workgroup testified to the NCVHS in July 2007, and recommended adoption of an acknowledgement transaction standard for inclusion with NCVHS' recommendation for the adoption of Version 5010, NCVHS did not include an acknowledgement transaction standard in its recommendations. Nonetheless, the fact that we have not adopted an acknowledgement standard does not preclude the industry from using Version 5010 to conduct the transaction between willing trading partners. We will consider the adoption of a standard for the acknowledgement transaction at the time we receive a recommendation from NCVHS.

Real-Time Eligibility

*Comment:* A few commenters stated that there was a business need for a real-time eligibility transaction standard for all participants in healthcare delivery. They stated that, without a national standard, varying approaches to real-time eligibility will be detrimental to providers and plans that do business on a national basis. The commenters identified a number of organizations such as WEDI, CAQH and Blue Cross Blue Shield of North Carolina that support real-time eligibility transactions.

*Response:* Similar to a standard for the acknowledgement transaction, adopting a standard for real-time eligibility transactions would have to be vetted through the standards adoption process described above. NCVHS did not include a real-time eligibility transaction standard in its recommendations, and we are unable to adopt one at this time.

HHS Funding the Purchase of TR3 Reports

When the Transactions and Code Sets rule was published, HHS negotiated a contract with the publisher of the Version 4010/4010A implementation guide to enable the industry to download the guides at no cost. This practice ended in 2006. At that time, very few downloads or copies were being ordered, and we had no complaints about individual providers, plans or clearinghouses paying the fee. HHS did not have a similar arrangement with NCPDP, so the industry has always paid for guides for those standards.

*Comment:* A few commenters suggested that HHS should pay for the industry to access copies of Version 5010. These commenters stated that small providers could not afford to buy the set of guides, which currently cost approximately $800 for the set, or $175 for each guide. Several other commenters expressed concern about the cost of the X12 TR3s and a new requirement that covered entities purchase these guides. Commenters noted that HHS underwrote the Version 4010/4010A guides on behalf of covered entities through that implementation effort and believe that it is the most beneficial way for covered entities to access and implement new versions.

*Response:* It is not uncommon for standards organizations to charge a fee for copies of their standards. NCPDP charges such a fee for their standards, which HHS has never covered for the industry. We do not agree that the price for the guides will negatively impact small providers because we think it is unlikely that small providers will find them useful in implementing Version 5010. We understand that small providers usually rely on software vendors to make their systems compliant, and that it is the vendors who will require the guides for programming. We expect that, as in the past, vendors and professional associations will provide necessary education and training for the provider staff on the system changes that will require operational changes. Software vendors typically have multiple clients, and we expect that they will only need to purchase one, or at most, just a few sets of the standards to program for all of their clients. Such multiple usages should defray the modest expense.

HIPAA Enforcement

At present, most formal compliance and enforcement activities for HIPAA are complaint-driven and complaint-based. Enforcement efforts are focused on investigating complaints to determine if a covered entity is in compliance.

*Comment:* We received a few comments recommending that HHS increase its enforcement efforts related to HIPAA transactions to ensure that health plans are adhering to the requirements of the X12 transactions. We received another comment suggesting stronger enforcement of the adoption of all of the standard transactions by all covered entities. One commenter said that, to date, only a subset of HIPAA-mandated transaction standards that facilitate EDI have been

implemented as required, which significantly decreases the benefits of standardization to the industry.

*Response:* Our complaint-driven enforcement process has been successful in obtaining compliance on a case-by-case basis, and we encourage covered entities to utilize the process. We understand that some of the standards have not been implemented because of their limited usefulness, or because of issues with implementation. We believe that, because the standards have been significantly improved, the standards we adopt here are more useful, and therefore will result in greater industry implementation. We have the authority to conduct compliance reviews at our discretion to evaluate compliance with any of the HIPAA requirements, and have done so already with respect to the security standards. We plan to expand our compliance review program in the future to include random reviews of compliance with the transaction standards as well.

Certification

*Comment:* We received several comments suggesting that HHS consider petitioning the Certification Commission for Healthcare Information Technology (CCHIT) to include Versions 5010 or D.0 in all products that would be expected to carry the upgraded standards in order to facilitate compliance with the final rule. Commenters believe this will be especially important for small covered entities in the process of purchasing software until the compliance date. They believe that, if purchasers are aware of the need to buy products that are certified to meet the incoming HIPAA requirements, conversion might be smoother and less expensive.

*Response:* Generally, CCHIT does not certify products for administrative transactions, and therefore we will not pursue this suggestion. Furthermore, HHS does not recognize certification of any systems or software for purposes of HIPAA compliance.

*H. Comments Considered Out of Scope*

We received a number of comments on subjects that were outside the scope of the proposed rule. We do not directly respond to those types of comments because we consider them to be outside the scope of this rule, but we wish to acknowledge them. We have summarized them in the following list:

- One commenter stated the final rule should clarify the relationship between HIPAA and the Family Educational Rights and Privacy Act (FERPA). The commenter stated that there are entities that are bound by both HIPAA and FERPA, and suggested that clarification is needed for situations where there are inconsistencies between the two laws.
- One commenter stated that HHS should agree to accept and utilize all diagnosis codes associated with an admission or an encounter, not just those accommodated within the limits first set by paper forms. The current practice of truncating numbers for diagnoses and procedures so that they are equal to what a paper claim supports causes problems for providers when they are trying to meet the ''Present on Admission'' (POA) requirement of providing adequate information about a patient's condition.
- One commenter recommended that HHS add a definition for real-time adjudication with regard to the 837 claim, 835 remittance advice and the 277 health care claim status transactions in this final rule. The commenter referenced the collaborative efforts between WEDI and X12 to provide a standard way to conduct real-time adjudication.
- One commenter requested that we address expectations related to § 162.925 regarding health plan incentives to health care providers for using direct data entry (DDE) transactions. The commenter said there are instances where health plans offer more information about eligibility and benefit information on Web sites than they do through the standard X12 270/271 transactions, which the commenter believes is an incentive for a provider to conduct a transaction using some means other than the standard transaction. The commenter requested clarification regarding the offer of more information through a non-standard transaction than in the standard transaction, even though the standard transaction contains the required amount of information. Since we did not address this issue in the proposed rule, we do not respond here, but may provide additional direction in a future Frequently Asked Question on the CMS Web site.

## III. Provisions of the Final Rule

This final rule incorporates the provisions of the proposed rule, with the following exceptions and changes: We proposed to adopt a compliance date for Versions 5010 and D.0 of April 1, 2010 for all covered entities. In this final rule, we adopt a compliance date of January 1, 2012 for Versions 5010 and D.0 for all covered entities. We revise § 162.1102, § 162.1202, § 162.1302, § 162.1402, § 162.1502, § 162.1602, § 162.1702, and § 162.1802 accordingly.

We proposed a compliance date of 24 months after the effective date of the final rule for the Medicaid pharmacy subrogation standard (Version 3.0) with an additional 12 months for small health plans. In this final rule, we indicate an effective date of January 1, 2010 for the provisions of 45 CFR Subpart S. This means that covered entities other than small health plans must be in compliance on January 1, 2012, while small health plans, which have an additional 12 months, must be in compliance on January 1, 2013.

In § 162.925, we add paragraph (a)(6) that precludes health plans from requiring an earlier compliance date than those adopted. Use of Versions 5010 and D.0 in advance of the mandatory compliance date is permissible, based upon mutual agreement by trading partners.

We adopt revisions to § 162.1102, § 162.1202, § 162.1302, § 162.1402, § 162.1502, § 162.1602, § 162.1702, and § 162.1802 to enable covered entities to engage in Level 2 testing by allowing for the use of both the old standard and the updated standard.

We allow covered entities to use either Version 4010/4010A, 5010, 5.1 or D.0 for billing retail pharmacy supplies and services, and reflect that policy in revisions to § 162.1102. We also revise the definition of ''standard transaction'' in accordance with our policy to allow for the dual use of standards, by replacing ''the applicable standard'' with ''an applicable standard'' at § 162.103

We proposed to clarify the descriptions for three standards: Enrollment and disenrollment, referral certification and authorization, and health care claims status and request. In the final rule we do so, by specifying the senders and receivers of those transactions in § 162.1301, § 162.1401 and § 162.1501.

In the proposed rule, at § 162.900, we stated that ASC X12N implementation specifications and the ASCX12 Standard for Electronic Data interchange Technical Report Type 3 were available from the Washington Publishing Company. In the final rule, we provide the correct address and Web site for obtaining the Version 5010 guides, from X12. Version 4010/4010A specifications may still be obtained from the Washington Publishing Company.

## IV. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995, we are required to provide 30-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and

approval. In order to fairly evaluate whether an information collection should be approved by OMB, section 350(c)(2)(A) of the Paperwork Reduction Act of 1995 requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

In this rule, we are finalizing the revisions to the information collection requirements that were announced in the proposed rule that was published on August 22, 2008 (73 FR 49742). Specifically, we are revising the currently approved information collection requirements contained in § 162.1102, § 162.1202, § 162.1301, § 162.1302, § 162.1401, § 162.1402, § 162.1501, § 162.1502, § 162.1602, § 162.1702, and § 162.1802 of this document. We believe that the revisions will have an impact on the burden (both hour burden and cost burden) associated with the aforementioned affected sections that are currently approved under OCN 0938–0866 with an expiration date of 7/31/2011. In addition to announcing the revisions in the proposed rule, we published a 60-day **Federal Register** notice on October 10, 2008 (73 FR 60296) that solicited public comments on the proposed revisions. No comments were received. Accordingly, we have submitted a revised information collection request to OMB for its review and approval of the revised information collection requirements. These requirements are not effective until approved by OMB.

If you wish to comment on these information collection and recordkeeping requirements, please fax your comments to 202–395–6974 or email your comments to *oira_submission@omb.eop.gov*. Please mark comments to the attention of the desk officer for CMS and indicate that they are in relation to OMB control number 0938–0866.

## V. Regulatory Impact Analysis

### *A. Overall Impact*

We have examined the impacts of this rule as required by Executive Order 12866 (September 1993, Regulatory Planning and Review), as amended by Executive Order 13258 (February 26, 2002) and further amended by Executive Order 13422 (January 18, 2007), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Social Security Act, the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4), Executive Order 13132 on Federalism, and the Congressional Review Act (5 U.S.C. 804(2)).

Executive Order 12866 (as further amended) directs agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more in any 1 year). Because we estimate that this rule will have economically significant effects, we prepared an RIA. We anticipate that the adoption of the new versions of the standards and the adoption of Version 3.0 would result in benefits that will outweigh the costs. Accordingly, we prepared a Regulatory Impact Analysis in the August 22, 2008 proposed rule that, to the best of our ability, presented the costs and benefits of the proposals. We did not receive any comments on the Regulatory Flexibility Analysis, and therefore provide a summary here. For details, we refer readers to the August 22, 2008 proposed rule at 73 FR 49757.

### *B. Regulatory Flexibility Analysis*

The Regulatory Flexibility Act (RFA) of 1980, Public Law 96–354, requires agencies to describe and analyze the impact of the rule on small entities unless the Secretary can certify that the regulation will not have a significant impact on a substantial number of small entities. In the health care sector, a small entity is one with between $6.5 million and $31.5 million in annual revenues or is a nonprofit organization. For the purposes of this analysis (pursuant to the RFA), nonprofit organizations are considered small entities; however, individuals and States are not included in the definition of a small entity. We attempted to estimate the number of small entities and provided a general discussion of the effects of the proposed regulation, and where we had difficulty, or were unable to find information, we solicited industry comment. We stated our belief that the conversion to Versions 5010 and D.0 would have an impact on virtually every health care entity. We did not receive any comments in response to our solicitation for comments.

In our analysis, we combined Versions 5010 and D.0 because these two standards will be implemented at the same time, and in some cases are dependent on each other. We provided examples in the August 22, 2008 proposed rule (73 FR 49758).

The summary table in this final rule includes the final cost estimates for Versions 5010, D.0 and 3.0 on all entities we anticipated would be affected by the rule. The data in that table were used in this analysis to provide cost information.

Because most health care providers are either nonprofit or meet the Small Business Administration's (SBA) size standard for small business, we treated all health care providers as small entities. For providers, we predicted that the changes would be minimal involving software upgrades for practice management and billing systems. We included pharmacies in the analysis, and considered some of them to be small businesses. We considered some health plans small businesses, but were unable to identify data for these entities, nor was any information submitted in response to our solicitation. We addressed clearinghouses and Pharmacy Benefit Managers (PBMs) in our discussion, though we did not believe that there were a significant number of clearinghouses that would be considered small entities. This was confirmed by a number of associations, including the Maryland Commission for Health Care. PBMs were excluded from the analysis because we had no data to indicate that they would qualify as a small entity. State Medicaid agencies were excluded from the analysis because States are not considered small entities in any Regulatory Flexibility Analysis.

Final Regulatory Flexibility Analysis (FRFA)

1. Number of Small Entities

In total, we estimated that there are more than 300,000 health care organizations that may be considered small entities either because of their nonprofit status or because of their revenues. The Business Census data shows that there are 4,786 firms considered as health plans and/or payers (NAICS code 5415) responsible for conducting transactions with health care providers. In the proposed rule's impact analysis, we used a smaller figure based on a report from AHIP. But for purposes of the RFA, we did not identify a subset of small plans, and instead solicited industry comment as to the percentage of plans that would be considered small entities. We identified

the top 78 clearinghouses/vendors in the Faulkner and Gray health data directory from 2000—the last year this document was produced. Health care clearinghouses provide transaction processing and translation services to both providers and health plans.

We identified nearly 60,000 pharmacies, using the National Association of Chain Drug Stores Industry Profile (2007) (*http://www.nacds.org*), and for the purposes of the initial regulatory flexibility analysis we are treating all independent pharmacies reported in the Industry Profile as ''small entities.'' The number of independent pharmacies reported for 2006 is approximately 17,000 entities. We specifically invited comments on the number of small pharmacies, but received none.

Based on Figure 2 of the Industry Profile, independent pharmacy prescription drug sales accounted for 17.4 percent of total pharmacy drug sales of $249 billion sales for 2006. Allocating the Versions 5010 and D.0 costs based on the share of prescription drug revenues to independent pharmacies (the small businesses), implementation costs are expected to range between $6.4 million and $13 million or 0.02 and 0.03 percent of revenues. These figures indicate that there is minimal impact, and the effect falls well below the HHS threshold of 3 to 5 percent specified in the HHS guidance on treatment of small entities (*see*: ''Guidance on Proper Consideration of Small Entities in Rulemakings of the U.S. Department of Health and Human Services'' *http://www.hhs.gov/execsec/smallbus.pdf.pdf*).

2. Costs for Small Entities

To determine the impact on health care providers we used Business Census data on the number of establishments for hospitals and firms for the classes of providers and revenue data reported in the Survey of Annual Services for each NAICS code. For other providers, we assumed that the costs to implement Version 5010 would be accounted for at the level of firms rather than at the individual establishments. Since we treated all health care providers as small entities for the purpose of the initial regulatory flexibility analysis, we allocated 100 percent of the implementation costs reported in the impact analysis for provider type. Table 2 shows the impact of the Version 5010 implementation costs as a percent of the provider revenues. For example, dentists, with reported 2005 revenues of $87.4 billion and costs ranging from $299 million to $598 million have the largest impact on their revenues of between 0.11 percent and 0.21 percent. We solicited comments specifically on the number of providers affected by the proposed rule, but received none.

We did not include an analysis of the impact on small health plans, because we were not able to determine the number of plans that meet the SBA size standard of $6.5 million in annual receipts.

In evaluating whether there were any clearinghouses that could be considered small entities, we consulted with three national associations (EHNAC, HIMSS and the Cooperative Exchange), as well as the Maryland Commission for Health Care, and determined that the number of clearinghouses that would be considered small entities was negligible. We identified the top 78 clearinghouses, and determined that they are typically part of large electronic health networks, such as Siemens, RxHub, Availity, GE Healthcare etc., none of which fit into the category of small entity. As referenced earlier, in a report by Faulkner and Gray in 2000, the top 51 entities were listed, and the range of monthly transactions was 2,500 to 4 million, with transaction fees of $0.25 per transaction to $2.50 per transaction. We determined that even based on these data, few of the entities would fall into the small entity category, and we did not count them in the analysis.

With respect to Version 3.0, we point out that, while we do not know how many health plans/payers will exchange the pharmacy subrogation standard with Medicaid agencies, those entities would be counted in the health plan category and addressed under the analysis for Versions 5010 and D.0. We did not provide a separate analysis in this section.

In sum, we assumed that the financial burden would be equal to or less than three percent of revenues. Based on the results of this analysis, we remain reasonably confident that the rule will not have a significant impact on a substantial number of small entities. As stated throughout this section, in spite of our request for comments on this analysis, we received none.

Table 2 below summarizes the impact of the rule on the health care industry.

TABLE 2—ANALYSIS OF IMPLEMENTATION OF THE BURDEN OF VERSIONS 5010, D.0 AND 3.0 ON SMALL COVERED ENTITIES

| NAICS | Entities | Total no. of entities | Small entities | Revenue or receipts ($ millions) | % Small entity receipts of total receipts | Version 5010/D.0 annual costs (in millions) | Small entity share of version 5010/D.0 costs (in millions $) | % Implementation cost revenue-receipts (costs/receipts) |
|---|---|---|---|---|---|---|---|---|
| 6221 | General Acute Care Hospitals (establishments) | 5,386 | 5,386 | 612,245 | 100 | 292–583 | ..... | .05–.10 |
| 6211 | Physicians (firms) | 189,562 | 189,562 | 330,889 | 100 | 136–272 | ..... | .04–.08 |
| 6212 | Dentists (firms) | 118,163 | 118,163 | 87,405 | 100 | 94–187 | ..... | .11–.21 |
| 44611 | Pharmacies (includes 5010 and D.0) | 56,946 | 17,482 | 249,000 (42,330 @ 17%) | 17.4 | 37–75 | 6.4–13 | .02–.03 |

In column 1 we display the NAICS code for class of entity. Column 3 shows the number of entities that are reported in the Business Census for 2006 or ''Chain Pharmacy Industry Profile.''

Column 4 shows the number of small entities that were computed based on the Business Census and Survey of Annual Service when the data was available. All health care providers were assumed to be small. We assumed that all independent pharmacies reported in Table 2 of the Industry profile are small entities.

Column 5 shows revenues that were reported for 2005 in the Survey of Annual Services, or in the case of pharmacies, in Figure 2 of the Industry profile. In the case of health plans and third party administrators, we used the consumer payments reported for private health insurance in 2006 in the National Health Expenditure accounts.

Column 6 shows the percent of small entity revenues.

Column 7 shows the implementation costs for Versions 5010, D.0 and 3.0

taken from Table 14a of the impact analysis and annualized.

Column 8 shows the costs allocated to the small entities based on the percent of small entity revenues to total revenues.

Column 9 presents the percent of the small entity share of implementation costs as a percent of the small entity revenues. As stated in the guidance cited earlier in this section, HHS has established a baseline threshold of 3 percent of revenues that would be considered a significant economic impact on affected entities. None of the entities exceeded or came close to this threshold.

We note that the impact in our scenarios is consistently under the estimated impact of 3 percent for all of the entities listed above, which is below the threshold the Department considers as a significant economic impact. As expressed in the Department guidance on conducting regulatory flexibility analyses, the threshold for an economic impact to be considered significant is 3 percent to 5 percent of either receipts or costs. As is clear from the analysis, the impact does not come close to the threshold. Thus, based on the foregoing analysis, we conclude that some health care providers may encounter significant burdens in the course of converting to the modified Versions 5010 and D.0. However, we are of the opinion that, for most providers, health plans, and clearinghouses the costs will not be significant.

3. Alternatives Considered

As stated in the August 22, 2008 proposed rule, we considered various policy alternatives to adopting Versions 5010, D.0 and 3.0, including not adopting the modifications, using staggered implementation schedules, allowing implementation delays for small entities, and waiting to adopt a later version of the X12 and/or NCPDP standards. We rejected all of these alternatives, resulting in the adoption of the standards, as proposed, with an alternate compliance date.

4. Conclusion

As stated in the HHS guidance cited earlier in this section, HHS uses a baseline threshold of 3 percent of revenues to determine if a rule would have a significant economic impact on affected entities. None of the entities exceeded or came close to this threshold. Based on the foregoing analysis, the Secretary certifies that this final rule will not have a significant economic impact on a substantial number of small entities.

Section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule would have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 603 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a metropolitan statistical area and has fewer than 100 beds. This final rule will affect the operations of a substantial number of small rural hospitals because they are considered covered entities under HIPAA, however, we do not believe the rule will have a significant impact on those entities, for the reasons stated above in reference to small entities. Therefore, the Secretary has determined that this final rule will not have a significant impact on the operations of a substantial number of small rural hospitals.

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates would require spending, in any 1 year, $100 million in 1995 dollars, updated annually for inflation. In 2008, that threshold is approximately $130 million. This final rule contains mandates that will impose spending costs on State, local, or tribal governments in the aggregate, or by the private sector, in excess of the current threshold. The impact analysis in the proposed rule addressed those impacts both qualitatively and quantitatively. In general, each State Medicaid Agency and other government entity that is considered a covered entity will be required to invest in software, testing and training to accommodate the adoption of the updated versions of the standards, and Version 3.0. UMRA does not address the total cost of a rule. Rather, it focuses on certain categories of cost, mainly those ''Federal mandate'' costs resulting from (A) imposing enforceable duties on State, local, or tribal governments, or on the private sector, or (B) increasing the stringency of conditions in, or decreasing the funding of, State, local, or tribal governments under entitlement programs.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications. This final rule will have a substantial direct effect on State or local governments, could preempt State law, or otherwise have a Federalism implication because, even though State Medicaid agencies will be converting to a modified version of an existing standard (Version 4010/4010A to Version 5010 and NCPCP 5.1 to NCPDP D.0) with which they are familiar, there are expenses for implementation and widescale testing. State Medicaid agencies are currently required to conduct pharmacy subrogation, and in accordance with this final rule, will be able either to use the new Medicaid pharmacy subrogation transaction standard or contract with trading partners and/or contractors who specialize in this field to fulfill its subrogation requirement. With respect to subrogation for pharmacy claims, we note that this final rule does not add a new business requirement for States, but rather mandates a standard to use for this purpose which will be used consistently by all States. There will also be expenditures for States as they convert from Version 5.1 to D.0 for other pharmacy transactions, and this transition will have implementation and testing costs as well, meaning there will be additional fiscal impacts on States based on this rule.

*C. Anticipated Effects*

The objective of this regulatory impact analysis was to summarize the costs and benefits of the following proposals:

- Migrating from Version 4010/4010A to Version 5010 in the context of the current health care environment;
- Migrating from Version 5.1 to Version D.0; and
- Adopting a new standard for the Medicaid subrogation transaction.

The following are the key issues that we believe necessitate the adoption of these modified standards and of a standard for Medicaid pharmacy subrogation:

- The current X12 and NCPDP standards were adopted in 2000 and do not reflect the numerous business changes that have emerged during that time.
- The current standards do not accommodate the use of ICD–10 codes.
- The standard for Medicaid pharmacy subrogation will significantly improve the efficiency of this process.

The remainder of this section provides details supporting the cost benefit analysis for each of the three above-referenced proposals.

In the August 22, 2008 proposed rule (73 FR 49761), we described the research conducted for us by Gartner, Incorporated (Gartner) to assess the costs and benefits associated with the

adoption of Version 5010. Details about Gartner's methodology were provided in the August 22, 2008 proposed rule, and a summary of the calculations and methodology is available on the CMS Web site at: *http://www.cms.hhs.gov/TransactionCodeSetsStands/Downloads/5010RegulatoryImpactAnalysisSupplement.pdf.*

In this section of the final rule, we summarize the key assumptions from the August 22, 2008 proposed rule, and discuss those with which commenters did not agree. In cases where we agreed with commenters, and changed our assumptions, we provide both the original and revised amounts, unadjusted for present value. The last section of the impact analysis contains the summary detailed tables with all of the costs and benefits recalculated to reflect the changes to the estimates for each of the standards and adjusted for present value. The analysis contained herein is presented at a high level. For a complete description of the analysis, see the Economic Impact Analysis in the docket of this final rule.

Additionally, although many commenters mentioned that we underestimated the costs, or overestimated the benefits of transitioning to the new versions, no substantive data or additional information was provided to counter our analysis, and therefore, though some changes have been made, they are not substantial, particularly for the benefits that are detailed in this final rule. However, based on the information we did receive, there are three items that changed, which affected some of the figures in the impact analysis: (1) The cost estimate was increased from between 20 percent and 40 percent of the Version 4010/4010A costs to between 25 percent and 50 percent; (2) the salary for provider billing specialist was reduced from $60 thousand per year to $50 thousand per year; (3) the timing for adoption of the auxiliary standards was changed to begin in calendar year 2013 instead of calendar year 2012; These three items represent cost and benefit changes that are reflected in this revised impact analysis, and we have updated the tables for each industry sector accordingly. One of the benefit categories, Cost savings or savings due to new users of claims standards, is not impacted by the aforementioned items. We do not repeat this entire explanation in each section, but rather refer the reader back to this introduction.

As noted in the preamble, the compliance date for Version 5010 has been changed to January 1, 2012, and the cost allocations have been updated in accordance with the new timeline. We assumed transition costs would occur in the fourth year of implementation (monitoring, maintaining, and adjusting the upgraded systems and related processes) and continue until all parties reach a ''steady state.''

While significant efforts were taken to ensure that the cost and benefits captured for this rule were accurate, there are a few key uncertainty factors that should be considered in reviewing the regulatory impact analysis:

- As detailed in the next section (Assumptions for Version 5010 Impact Analysis), the primary driver for all of the cost estimates was the expected range of costs for all covered entities relative to those same costs for implementation and transition to Version 4010.
- As detailed in the next section (Assumptions for Version 5010 Impact Analysis), one of the key drivers for all of the benefit estimates was increased use in electronic transactions. In all cases, HHS evaluated the industry feedback and used the conservative estimates for expected uptake in the electronic transactions so as to not inflate the benefits.
- As explained in the section on Version D.0, there is uncertainty as to the complexity and the number of systems that will be affected, and industry experts made their best estimates on the possible impacts to their constituents.

Assumptions for Version 5010 Impact Analysis

In calculating the costs and benefits, Gartner made a number of assumptions, based on interview data and secondary research. We outlined the key assumptions used to support Version 5010 impact analysis in the August 22, 2008 proposed rule (73 FR 49762).

Gartner projected the annual increase in the number of claims at four percent, and used these figures to calculate the provider benefits. We outlined annual claim volume projections in the August 22, 2008 proposed rule (73 FR 49762), and did not receive any comments on those figures.

Gartner estimated the current adoption rate for each of the HIPAA standards, and the projected rate of adoption for each of the modified versions of the standards over the planning horizon. We outlined those rates in the August 22, 2008 proposed rule (73 FR 49763). These figures were used to calculate the benefits for healthcare industry.

*Comment:* We received a few comments disagreeing with our assumptions about the increased use of auxiliary transactions. They stated that there will not be an automatic increase in the usage/volume of the auxiliary transactions, because the industry is still establishing a clear business need for these less widely used transactions (which are required for plans, but voluntary for providers). Auxiliary transactions are those that supplement or support claims information, including eligibility, enrollment and disenrollment, referral requests and authorizations and premium payments. Commenters also stated that, because these transactions were not useful in Version 4010/4010A, there is still some hesitancy to use Version 5010 until the transactions can be evaluated. Because efforts will be focused on implementing the claims and eligibility transactions for Version 5010, commenters stated that it may take industry longer to schedule testing for the auxiliary transactions.

*Response:* Gartner conducted additional discussions with industry experts regarding the original assumptions in the August 22, 2008 proposed rule. These experts acknowledged that providers that do not now use these transactions will be focusing all their initial efforts on implementing the key claims transactions—claims and remittance advice—and that they would likely focus on implementing the auxiliary transactions later. Accordingly, we changed the benefits realization assumption for auxiliary transactions to start in year 2013 instead of 2012. We do not agree with the few commenters who stated there would be no increase in the use of auxiliary transactions. In fact, the Gartner interviewees did not veer from their original statements that the auxiliary transactions would be used by more providers, albeit after initial implementation of the core transactions for claims and remittance advice. An association for physicians, in its comments, stated that these transactions would be increasingly used because of the improvements in the standards themselves and increased streamlining of various administrative processes.

The total benefits (low) across the industry declined from $18,635 million to $15,896 million.

*Comment:* We received a comment from a government health program stating that it did not agree with our savings/benefits assumption of reduced phone calls. The commenter explained that the salary savings/benefit has historically been found to be false savings unless personnel positions were actually eliminated.

*Response:* We disagree with the comment. Although personnel positions may not be eliminated, these personnel can be assigned to other tasks; in this case, the benefit is cost avoidance. Our estimates are based on cost avoidance, not personnel reductions.

General Assumptions for the Cost-Benefit Analysis for Providers and Health Plans

We outlined the key assumptions used to develop the cost benefit analysis for each of the provider segments—hospitals, physicians, pharmacies, and dentists as well as the health plans in the August 22, 2008 proposed rule (73 FR 49763).

Explanation of Cost Calculations

To determine the costs for each subsegment (that is, providers and health plans), we established an estimate for what the total approximate Version 4010/4010A costs were for an individual entity within that subsegment (based on the interviews and other data available through research—*see* 73 FR 49761) and then applied an estimated range of 20 to 40 percent of those costs to come up with estimated low and high costs for Version 5010. Additional information about the cost calculations and Gartner methodology are available in our supplemental document on the CMS Web site at: *http://www.cms.hhs.gov/TransactionCodeSetsStands/Downloads/5010RegulatoryImpactAnalysisSupplement.pdf.*

*Comment:* As stated above, a number of commenters disagreed with our assumptions concerning the level of effort necessary to migrate to Version 5010, in comparison with the initial implementation costs for Version 4010/4010A, and believed the costs to be significantly higher than our projections. Although no commenters actually provided a cost figure, a small number of commenters wrote that it would take 50 to 75 percent of the initial implementation effort to migrate to the new versions. The rationale provided was that:

(1) Organizations will have to operate dual systems through both testing and implementation phases as different trading partners migrate at different times.

(2) Additional considerations in the salary cost assumptions such as real estate, utilities, phone, computer systems, infrastructure, etc., to represent total cost of employee should be taken into consideration.

Other commenters supported our assumptions regarding costs of operating dual systems through both testing and implementation phases. These commenters explained that there may be additional hardware costs to upgrade existing equipment to manage the dual use period, or enhanced functionality necessary when upgrading to new versions of software ready to handle the new versions. Another commenter disagreed with our statement that little or no transmission costs would be required to comply with the new regulation. The commenter said that new transmission costs will be created with new trading partners and new or increased number of transactions. Another commenter stated that, while there would be a number of one-time costs to implement Version 5010 (for business flow changes, software procurement or customized software development, etc.), they did not agree that the system testing costs would account for 60 to 70 percent of all costs, but did not provide any additional detail for their dissension. In sum, while we received a variety of comments, none provided specific cost or implementation data to support their statements.

*Response:* We agree that the industry will need to operate dual systems to process both versions of the standards, and that transmission costs will increase. The implementation of Version 4010/4010A required extensive remediation of applications; development of external support capability to deal with expanded code lengths; different handling of coordination of benefits; and a variety of other business changes. It further involved the first implementation of X12 transaction formats for many providers, health plans and clearinghouses. In addition, many providers switched from paper to electronic transmission concurrent with this change. The changes going from Version 4010/4010A to Version 5010 are far less extensive on the whole, even though there are a host of content and format changes. While we acknowledge the need to support both formats, the time spent dealing with errors and reworking business flows should not be nearly as great as the experience of implementing Version 4010/4010A. This difference in the scope of the changes between implementation of Version 4010/4010A and Version 5010 was one of the key bases for the original estimates that we obtained when surveying industry segments in preparing the August 22, 2008 proposed rule.

With regard to the comments regarding dual hardware, many transaction mapping products are capable of supporting more than one variant of the transaction format using the same hardware and communications channels. Although some additional transaction volume will be required for testing and parallel operations, HHS has concluded that there will be an incremental need for added hardware and communications capacity to support submitting all transactions in both formats during the conversion period.

With regard to the comment regarding additional salary cost assumptions, all cost estimates provided in the analysis presented in the proposed rule (73 FR 49762) included the full set of overhead and added personnel costs including real estate, utilities, phone, computer systems, infrastructure, etc. These items are considered to be part of the fully loaded costs to implement and maintain the Version 5010 transactions and would also be considered to be costs avoided in the benefit period once all parties have implemented the new version.

While most commenters did not provide specific data regarding additional costs, we nonetheless acknowledge that commenters generally believed our estimates to be too low, and did note specific areas of concern. Accounting for all of the new cost considerations, we have adjusted our assumption to a range of 25 to 50 percent of the Version 4010/4010A implementation costs to move to Version 5010. The total costs (low estimate) incurred by the whole industry increased from $5,656 million to $7,717 million, unadjusted for present value.

In the August 22, 2008 proposed rule (73 FR 49764), we show Gartner's estimates of the percent of the total costs allocated to each cost category (for example, testing and training) for the provider and plan segments. As discussed above, we used industry comments to revise the estimates for hardware and transmission costs. Table 3 reflects the new allocations of the percent of the total costs to each cost category.

TABLE 3—PERCENTAGE AND TOTAL AMOUNTS FOR COST ITEMS USED FOR VERSION 5010 CALCULATIONS—PROVIDERS AND HEALTH PLANS

| Cost item | Percent of total costs | |
|---|---|---|
| | Providers (percent) | Health plans (percent) |
| Hardware Procurement | 10 | 10 |
| Software Costs | 10 | 7.5 |
| Transmission Costs | 2.5 | 2.5 |
| New Data Collection | 0 | 0 |
| Customized software development | 5 | 2.5 |
| Testing Cost | 60 | 65 |
| Training Costs | 2.5 | 2.5 |
| Transition Costs | 10 | 10 |
| Totals | 100 | 100 |

Original source: Gartner interviews and secondary research.

Explanation of Benefits and Savings Calculations

In our analysis, we assumed that benefits would accrue in three categories which were described and explained in detail in the August 22, 2008 proposed rule (73 FR 49764). For ease of reference, they were labeled: (1) *Better standards* or savings due to improved claims standards; (2) *Cost savings* or savings due to new users of claims standards; and (3) *Operational savings* or savings due to increased auxiliary standards usage.

For ease of reference, we repeat the explanation of the three savings categories:

(1) Better standards or savings due to improved claims standards: The improvements in Version 5010 that would reduce manual intervention to resolve issues related to the claim or remittance advice, due to ambiguity in the standards;

(2) Cost savings or savings due to new users of claims standards: Increased use of electronic transactions for claims and remittance advice that would accrue to parties who had previously avoided the electronic transactions because of their deficits and shortcomings; and

(3) Operational savings or savings due to increased auxiliary standards usage: Increase use of auxiliary transactions through EDI that would result from a decrease in manual intervention to resolve issues with the data (handled through phone calls or correspondence).

The August 22, 2008 proposed rule (73 FR 49765) details the business activities, such as manual interventions and phone calls, that make up the calculations for two of the categories of projected savings: *Better standards* or savings due to improved claims standards and *Operational savings* or savings due to increased auxiliary standards usage. As stated, only two of the three benefit categories are impacted by the revised assumptions.

*Comment:* We received one comment disagreeing with our assumption that provider billing specialist yearly costs are $60,000. The commenter stated that the billing specialist yearly cost, on average across the country, is not higher than $50,000.

*Response:* We agree with the comment after performing additional research regarding this assumption, and as a result, have changed our estimate regarding yearly costs for a provider billing specialist from $60,000 to $50,000. Based on this change, the total benefits (low estimate) across the industry declined from $18,635 million to $15,896 million, unadjusted for present value.

The benefits category, ''*Cost savings,* or savings due to new users of claims standards,'' does not change as a result of our revised calculations. The revised provider billing specialist salary assumption only affects the benefit calculations for benefit category, ''*Better standards* or savings due to improved claims standards'' and the revised benefits realization assumption for auxiliary transactions only changes the benefit calculation for benefits category, ''*Operational savings* or savings due to increased auxiliary standards usage''. However, the entire benefit projection changes because of the revised compliance date.

**1. Health Care Providers**

In the August 22, 2008 proposed rule (73 FR 49765), we reiterated that providers are not required by HIPAA to conduct HIPAA transactions electronically, but if they do, they must use the standards adopted by the Secretary. Providers that conduct these transactions electronically would be required to implement Version 5010 of those transactions.

Hospitals

In the August 22, 2008 proposed rule, we calculated that the total cost for all hospitals to implement Version 5010 would be within a range of $932 million to $1,864 million (73 FR 49767). Based on the revised cost assumptions outlined earlier (increased rate of 25 to 50 percent), the new estimate of total costs for all hospitals to implement Version 5010 will be within a range of $1,165 million to $2,331 million, unadjusted for present value.

Hospitals would realize savings and benefits in the same three categories we identified in the August 22, 2008 proposed rule (73 FR 49766). In the proposed rule, we calculated that the savings due to better standards were estimated to be a low of $403 million. Cost savings due to an increase in use of the electronic claims transactions (837 and 835) were estimated at a low of $66 million. Operational savings due to an increase in the use of auxiliary transactions were estimated at $1,314 million.

Based on the revised benefit assumptions outlined earlier, the new estimate for minimum savings due to better standards is $348 million and operational savings due to increase in the use of auxiliary claim transactions are $1,132 million, unadjusted for present value. The cost savings benefit category is not impacted by the revised benefit assumptions.

Physicians and Other Providers

We outlined the key assumptions used to develop the cost benefit analysis for physicians and other providers segment in the August 22, 2008 proposed rule (73 FR 49767), and calculated that the total cost for all physicians and other providers segment to implement Version 5010 would be within a range of $435 million to $870 million. Based on the revised cost

assumption outlined earlier, the new estimate of total cost for physicians and other providers segment to implement Version 5010 is between $544 million to $1,088 million, unadjusted for present value.

In the proposed rule, we calculated that the savings due to better standards was estimated to be a low of $1,612 million. Cost savings due to an increase in use of the electronic claims transactions (837 and 835) were estimated at a low of $270 million. Operational savings due to an increase in the use of auxiliary transactions were estimated at $5,251 million.

Based on the revised benefit assumptions outlined earlier (change in salary and later adoption of auxiliary transactions), the new estimate for physician savings due to better standards is $1,392 million and operational savings due to increase in the use of auxiliary claim transactions are $4,443 million, unadjusted for present value. As mentioned earlier, the benefit category cost savings is not impacted by the revised benefit assumptions.

Dentists

In the August 22, 2008 proposed rule, we acknowledged that the dental community has not yet widely adopted the HIPAA standards, in large part because the standards did not meet their practical business needs, particularly for claims and remittance advice. We assumed that the costs for implementing Version 5010 would largely fall on vendors as a cost of doing business, as they support the majority of dentists. We outlined the key assumptions used to develop the cost benefit analysis for dentists segment in the August 22, 2008 proposed rule (73 FR 49768). We received a few general comments from the dental community regarding our estimates of the dental profession. We did not receive any actual cost data from any organization or practitioner.

*Comment:* We received one comment clarifying a figure in Table 18 in the supplement document posted on the CMS Web site in October 2008. The clarification is that the number of dentist practices (outlined in Table 18) does not include a one-to-one relationship between dentists and their office, so the calculation assumes too large a number. The commenter did not provide a figure however.

*Response:* We agree with the clarification and distinction, and have updated the table in the supplement to indicate the numbers were for individual dentists. However, in HHS's opinion, the current cost estimates are not overstated. We derived the cost per dentist based on input provided by the industry, which reflected office costs, in keeping with the other portions of the analysis.

*Comment:* We received one comment clarifying another data point—in Table 19 in the supplement document posted on the CMS Web site in October 2008. The clarification is that the size of most dental practices is less than 5. In Table 19, the practice size categories were too large (''50–100 physicians'' and ''100 + physicians,'') for dentistry, and should have reflected a smaller number at the lower end.

*Response:* We agree with the clarification, and have updated the table to represent the data collected from the industry. However, the calculation of the costs and benefits are not affected by this comment.

In the August 22, 2008 proposed rule (73 FR 49768), we calculated that the total cost for dentists to implement Version 5010 would be within a range of $299 million to $598 million. Based on revised cost assumption outlined earlier, the new revised estimate of total costs for the dentist segment to implement Version 5010 is within a range of $373 million to $747 million, unadjusted for present value.

Based on the revised benefit assumptions outlined earlier, the new estimate for savings due to better standards is $236 million and operational savings due to increase in the use of auxiliary claim transactions are $753 million, unadjusted for present value. As mentioned earlier, the benefit category cost savings is not impacted by the revised benefit assumptions.

Pharmacies

Pharmacies will transition to greater use of Version 5010 when the final rule becomes effective, specifically for the 835 transaction (remittance advice). For retail pharmacy claims, pharmacies primarily use the NCPDP standard, Version 5.1. Since we are replacing Version 5.1 with Version D.0 in this regulation, and many of the system changes, costs and benefits for implementing both Version 5010 and Version D.0 will result from related efforts, we combined the impact analysis for Version 5010 and Version D.0. That analysis is detailed later in this analysis.

*Comment:* We received a comment from a pharmacy chain that identified a pharmacy segment that was not considered in the regulatory impact analysis. The commenter stated that there are retail pharmacies that are not considered a chain store, and would not fall under the category of independent pharmacies. In addition, the commenter provided representative costs incurred by a typical retail pharmacy in this segment. This commenter said that the cost of implementation of both the standards (Versions D.0 and 5010) would be approximately $250,000, with 90 percent of the cost associated with the upgrade from Version 4010/4010A to Version 5010.

*Response:* Although the commenter had identified representative costs, it did not provide additional information regarding the number of retail chains that fall in this segment. We were, therefore, not able to re-model the impact analysis based on the additional information provided by the commenter. Furthermore, the impact analysis for pharmacies is handled in the section for Version D.0 and we believe those figures are representative of the segment overall.

Health Plans

In the August 22, 2008 proposed rule (73 FR 49769), we outlined the key assumptions used to develop the cost benefit analysis for the health plans segment. We calculated that the total cost for health plans to implement Version 5010 would be within a range of $3,604 million to $7,209 million. Based on the revised cost assumption outlined earlier, the new estimate of total cost for health plans to implement Version 5010 is to be within a range of $4,505 million to $9,011 million, unadjusted for present value.

In the August 22, 2008 proposed rule (73 FR 49769), we calculated that the savings due to better standards were estimated at a low of $1,283 million. Cost savings due to an increase in use of the electronic claims transactions (837 and 835) were estimated at a low of $111 million. Operational savings due to an increase in the use of auxiliary transactions were estimated at $4,386 million. We outlined the Version 5010 cost benefit summary for health plans segment (73 FR 49769).

Based on the revised benefit assumptions outlined earlier, the new estimate for savings due to better standards is $1,093 million, and operational savings due to increase in the use of auxiliary claim transactions are $3,711 million, unadjusted for present value. As mentioned earlier, the benefit category cost savings is not impacted by the revised benefit assumptions.

Government Plans

We outlined the key assumptions used to develop the cost benefit analysis for government plans segment in the August 22, 2008 proposed rule (73 FR 49770), and calculated that the total

costs for government plans segment to implement Version 5010 would be within a range of $252 million to $481 million. Based on the revised cost assumption outlined earlier, the new estimate of total costs for the government plans segment to implement Version 5010 is within a range of $314 million to $601 million, unadjusted for present value.

In the August 22, 2008 proposed rule, we estimated that savings due to better standards would be a low of $279 million. Cost savings due to an increase in use of the electronic claims transactions (837 and 835) were estimated to be a low of $24 million. Operational savings due to an increase in the use of auxiliary transactions were estimated at $953 million. We outlined the Version 5010 cost benefit summary for government plans segment (73 FR 49770).

Based on the revised benefit assumptions outlined earlier, the new estimate for savings due to better standards is $238 million and operational savings due to increase in the use of auxiliary claim transactions are $807 million, unadjusted for present value. As mentioned earlier, the benefit category cost savings is not impacted by the revised benefit assumptions.

Clearinghouses and Vendors

We outlined the key assumptions used to develop the cost benefit analysis for clearinghouses and vendors segment in the August 22, 2008 proposed rule (73 FR 49770), and calculated that the total costs for clearinghouses to implement Version 5010 would be within a range of $37 million to $45 million.

*Comment:* We received a comment from a large clearinghouse stating that our cost assumptions were significantly understated, and that their costs to implement Version 5010 would be at least $3.5 million, and would be affected specifically by the amount of testing that would be required with trading partners—both providers and health plans.

*Response:* We agree with the comment based on several additional interviews with large and medium clearinghouse representatives. In preparing the final rule, we did some additional analysis on a larger sample of the 162 clearinghouses that we included in our estimate. In this analysis we found that the cost per clearinghouse would be driven primarily by the number of trading partners with whom the clearinghouses would need to test Version 5010 transactions. The number varied greatly between the smaller clearinghouses and the larger ones and, therefore, created a range of costs for implementation and transition to Version 5010 based on this variable. Using this analysis, we increased our estimates and came up with an average implementation cost for each clearinghouse of $1 million (low) and $1.21 million (high) (up from a range of $0.23 million to $0.28 million). The total costs (low) for the clearinghouse segment increased from $37 million to $160 million.

Based on the comments, we revised our estimate of the total costs for the clearinghouse segment to implement Version 5010 to be within a range of $160 million to $196 million, unadjusted for present value.

In the August 22, 2008 proposed rule (73 FR 49771), we stated our assumption that there would be no benefits for clearinghouses. We did not receive any comments on this assumption, but feedback from industry interviews supports our belief that other than business stability, there are no other benefits for clearinghouses.

Other Comments Pertaining to Cost Estimates

*Comment:* We received a few comments requesting that HHS review the WEDI Cost Benefit Analysis (CBA) documents prepared in CY2007 and consider the industry projections of Version 5010 implementation costs from that analysis.

*Response:* We reviewed all of the CBA documents forwarded by WEDI. We were able to make some qualitative inferences based on the CBA survey responses and used those to solicit additional feedback from industry leaders regarding the CBA findings and to better augment the regulatory impact analysis. The input from this analysis helped inform the changes we have outlined in the final rule. However, we did not take the CBA estimates in their current form because:

- The CBA does not capture a breakdown of costs by healthcare sub segment but rather at the aggregate. Although the CBA summarizes the survey responses, it does not include analysis based on the survey responses. For example, the CBA captures the survey responses regarding participant details and the cost details. It does not tie the cost by survey participant as to establish a clear basis for comparison across organizations of similar size and type.
- It is difficult to develop Version 5010 costs based on the WEDI CBA because each analysis was conducted by transaction. For example, there are three analyses, one for each transaction: 835, 837 and 276/277. The costs outlined in the CBA have a high potential for overlap. In addition, participants are different for each survey. For example: 837 survey participants include four long term care health plans while 835 survey participants did not include any health plans.
- The survey results were not from a controlled sample. The depth of the survey respondent's understanding of the impact of Version 5010 was unclear. The lack of attribution and ability to contextualize survey responses makes it difficult to use the WEDI CBA directly; the utility of the data is extremely limited because of the small number of respondents, the uncertainty of the responses (over ⅓ of the payer, provider and vendor responders answered ''not sure'' when asked to estimate the costs for new software, upgrading of existing software, and custom solutions), and the lack of consistency of respondents across surveys.

As a result of these factors, this final rule is informed by the qualitative input from the WEDI CBA, but relies on the specific cost benefit study performed by Gartner to prepare the regulatory impact analysis for the August 22, 2008 proposed rule to adopt Version 5010.

*Comment:* One commenter stated that costs estimated to implement Version 5010 were 150 percent of the costs incurred during NPI implementation.

*Response:* We understand the context of the comment, although the commenter did not provide any data on which we could conduct any analysis or comparison. Since the commenter did not provide baseline data, a specific analysis could not be done to help us consider revising our cost estimates further.

*Comment:* We received a few comments requesting that HHS use the actual Version 4010/4010A implementation costs incurred by Medicare and Medicaid to estimate the truer costs to implement Version 5010.

*Response:* We acknowledge the comment, but do not provide a specific number for the Version 4010/4010A implementation costs incurred by Medicare and Medicaid. The budgetary process used by Medicare and Medicaid allocates funds for all approved Health Information Technology initiatives, and those estimates were used in our analysis, as was other data obtained from the industry at large. With respect to Medicare expenditures specifically, funds are allocated to the contractors for purposes of all updates and releases each year. Medicaid agencies do not report on a specific implementation, but rather track all system changes for purposes of federal cost sharing.

*Comment:* We received one comment requesting that HHS examine the costs for providers who must submit electronic information to HIPAA-exempt payers such as auto insurance, workers' compensation, property and casualty insurers who are not required to accept the HIPAA standard transactions. These providers must operate separate systems to support the requirements of covered and non-covered entities.

*Response:* This is consistent with current practice. These referenced entities have never been covered under HIPAA; there are already processes and systems being used to submit claims to different payer types. The commenter did not submit any data with respect to claims volumes or costs to help support the statement that these costs are unique and need to be examined.

Version D.0 (and Version 5010 for pharmacies)

In this section of the impact analysis, we summarize the key assumptions from the August 22, 2008 proposed rule, and discuss those with which the commenters disagreed. In cases where we agreed with the commenters and changed our estimates, revised tables are provided. In cases where we did not change our assumptions or estimates, the table from the August 22, 2008 proposed rule is not repeated. The last section of the impact analysis contains the summary detailed tables with all of the costs and benefits recalculated to reflect the changes. In general, pharmacy chains, health plans and PBMs believed that our cost estimates were too low, and provided modest justification for their position, but no entity provided actual data that could be used to adjust our estimates with precision. Based on the comments, we made some changes to our original assumptions and estimates for the cost of implementing Versions D.0 for pharmacy benefit managers.

As stated in the preamble, there was consensus that we should adopt Version D.0 to replace Version 5.1. No commenters disagreed with our estimates of the number of organizations and professionals affected by this rule, and there was also no disagreement about the estimate of more than 2.3 billion prescriptions annually.

*Costs*

a. Chain Pharmacies

The retail pharmacy industry would be the most impacted by the transition from Version 5.1. to Version D.0. In the August 22, 2008 proposed rule, we reported that one large national pharmacy chain estimated that it spent approximately $10 million when it converted to Version 5.1. In comparison, this chain estimated that corporate-wide costs for the conversion to Version D.0, including programming, system testing and personnel training, would be around $2 million per chain. Another large national pharmacy chain estimated its migration costs from Version 5.1 to Version D.0 would be $1.5 million. We solicited industry input in preparation for the proposed impact analysis, and the overall initial industry input for conversion to D.0 ranged from $100,000 for a small pharmacy chain to $1 million for large national pharmacy chains. Based on this information, we estimated implementation costs to be $20 million for large national pharmacy chains, and $18 million for small chains, for a total of $38 million.

*Comment:* We received a few comments disagreeing with our original cost estimates. One large chain estimated their cost at $4.9 million over two years but did not provide specifics. Another commenter estimated implementation costs of $2 million for small chains with costs increasing based on the size of the chain, but indicated that this estimate included both Version D.0 and Version 5010 costs.

*Response:* The few comments we received on this topic did not provide enough detail to permit us to assess them, and in one case the estimate did not distinguish between Version D.0 and Version 5010 costs. We retain our original estimates of $100,000 per small pharmacy chain and $1 million per large pharmacy chain company, unadjusted for present value. We estimate that these costs would be spread over the first two years of implementation of Version D.0.

b. Independent Pharmacies

In the August 22, 2008 proposed rule, we stated that independent pharmacies would incur costs resulting from software upgrades to accommodate Version D.0. We stated that we believed that maintenance fees would increase slightly, as vendors pass along their cost of the upgrade to the pharmacy. Based on industry input, we estimated that the average monthly maintenance contract between a pharmacy and a vendor amounts to a range of $400 to $800 per month per pharmacy with an additional percent for maintenance fee increases attributable to the conversion to Version D.0. Our original estimate per pharmacy was a range of $540,000 to $1,080,000 based on 18,000 independent pharmacies.

We did not receive any comments from any independent pharmacist or from any of their associations; therefore we stand by our original assumptions. We have modified the dates for those costs, in accordance with the revised compliance schedule.

c. Health Plans and PBMs

In the August 22, 2008 proposed rule (73 FR 49773), we stated that health plans should see minimal changes in their operations and workflows between Version 5.1 and Version D.0. We estimated the cost for large PBMs to migrate to Version D.0 to be approximately $1 million to $1.5 million per large national PBM, and approximately $100,000 for specialty PBMs. Our total estimated costs for health plans and PBMs ranged between $3.6 and $10.6 million per plan based on the size of the PBM.

*Comment:* We received a few comments suggesting that we understated the cost for health plans and PBMs to transition to Version D.0. While commenters agreed with our assessment of the consolidation of the PBM industry nationwide, they claimed that we did not account for the effect on a large PBM. Commenters explained that maintenance of multiple platforms results in increased complexities of operations and upgrades. One commenter estimated that costs for their upgrades would be $11 million, and, unlike the upgrades to the retail systems, they stated that few if any benefits will result from the costs.

Another commenter expanded on the cost issues, stating that the business requirements for commercial and Medicare Part D clients have required significant changes to the claim standard. They stated that the requirements affect all of the logic associated with the new fields which must be accommodated. They explained that even the customer service screens will require revision and that the representatives will require training on the new fields and the benefit changes so that they can answer beneficiaries' questions correctly. They estimate their total cost to be in excess of $10 million dollars.

Another commenter challenged our assumption that health plans and PBMs should see minimal changes in their operations and workflows between Version 5.1 and Version D.0., stating that Version D.0 requires additional data reporting related to the eligibility or subrogation/secondary plan aspects of the transaction, and that this represents a significant workload.

*Response:* When we prepared our original cost estimates, we treated the large PBMs the same as a large chain pharmacy. We did not completely

account for the complexity that the systems changes would present to large PBMs. At the time, we allowed for changes to be made on only one operating platform, while commenters pointed out that as many as seven platforms might need to be updated. We agree with commenters that large PBMs have complex systems that often include more than one platform, and that such comprehensive system upgrades can be more costly. Based on the comments, we have revised our cost projections. We amend our estimates from $2 million to $10.5 million for each large PBM company. Since we did not receive any comments from the smaller specialty PBMs, we leave our original assumption as stated in the August 22, 2008 proposed rule. Thus, our cost estimates have increased to $42 million for the large PBMs, and $3.6 million for the remaining small chains, for a total of $45.6 million, unadjusted for present value. We estimate that these costs would be incurred during the first two years of implementation.

d. Vendors

In the August 22, 2008 proposed rule (73 FR 49772), we solicited industry and stakeholder comment on the assumptions that vendor costs will be passed on to the customer over time, and solicited feedback on actual costs for vendor software upgrades and impact on covered entities, including the conversion of historical data. We received no comments from vendors related to their costs to upgrade to Version D.0 and therefore make no changes to this section. The figures from the proposed rule will be included in the summary table at the end of the impact analysis.

*Benefits*

In the August 22, 2008 proposed rule (73 FR 49742), we assumed that the benefits of converting to Version D.0 would accrue over several years, beginning in 2012. For a full overview of the benefit assumptions, refer to the discussion in the August 22, 2008 proposed rule at 73 FR 49773–49778.

a. Pharmacies

In the August 22, 2008 proposed rule (73 FR 49742), we said pharmacies need Version D.0 to process Medicare Part D claims more efficiently, and with fewer workarounds, particularly with respect to processing coordination of benefits claims.

*Comment:* We received a few comments on our benefit assumptions. One large pharmacy chain commented that, while they do not disagree that there will be benefits and savings following complete implementation of Version D.0, they are concerned that HHS has overstated those savings. The commenter recognized that the use of Version D.0 will decrease audit risks, however the savings assumption by HHS failed to recognize other gaps that will continue to exist in the outpatient health care system, specifically relative to the coordination of benefits.

Another commenter said that some of the savings numbers are so small (for example, the 1.1 percent of time of a pharmacist being spent on benefit issues), that they become hard to validate. Commenters did not provide any alternative data to show what the benefits to the pharmacies would be in their view.

*Response:* As we stated in the August 22, 2008 proposed rule (73 FR 79744), we based our assumptions on a study funded by the National Association of Chain Drug Stores (NACDS), ''Pharmacy Activity Cost and Productivity Study'' (*http://www.nacds.org/user-assets/PDF_files/ arthur_andersen.PDF* ). In projecting the growth in the number of pharmacies over the next 9 years, we used data from the NACDS, ''Community Retail Pharmacy Outlets by Type of Store, 1996–2006'' (*http://www.nacds.org/userseets/pdfs/facts_resources/2006/Retail_Outlets2006.pdf* ). Since we did not get any new data on the benefits, we stand by our assumptions and make no changes to the benefit data.

Health Plans and PBMs

We assumed that if pharmacists and technicians realize productivity savings as a result of the use of Version D.0, then conversely, health plans and PBMs would realize commensurate savings though a reduction in pharmacist and technician calls to customer service representatives at health care plans and PBMs. For a more detailed discussion of these savings through reductions in pharmacist and technician calls to customer service representatives at health plans and PBMs, please refer to the August 22, 2008 proposed rule (73 FR 49778).

*Comment:* One commenter stated that they felt that there are few if any benefits that will result from the cost of upgrading their system to Version D.0, however they did not expand on this statement or offer any alternative information.

*Response:* When estimating the benefits accrued to dispensers, we solicited industry and stakeholder comments on our assumptions. Although we received one comment stating that there were few, if any benefits to upgrading to Version D.0, the commenter did not provide us with any other data to refute what we originally proposed. Since most commenters did not dispute our assumptions, we do not make changes in the final rule.

Version 3.0 (Medicaid Pharmacy Subrogation)

As stated in the impact analysis for Version 5010 and Version D.0 above, in this section, we summarize the cost and benefit assumptions from the August 22, 2008 proposed rule, and discuss those with which the commenters disagreed. In cases where we agreed with the commenters and changed our estimates, revised tables are provided. The last section of the impact analysis contains the summary detailed tables with all of the costs and benefits recalculated to reflect the changes.

There was consensus that we should adopt Version 3.0, and we received no comments opposing our cost or benefit assumptions or estimates. However, to accommodate the change in effective and compliance dates for Version 3.0, we have made modifications to each of the tables presented in the proposed rule, and re-published them below.

In the August 22, 2008 proposed rule (73 FR 49779), we said that approximately 37 States were already billing a major portion of their Medicaid pharmacy subrogation claims electronically. Of those 37 States, 33 of them were using a contingency fee contractor to bill their (electronic) claims. The other four (out of 37) States were billing electronically without the use of a contractor. The remaining 14 States were still billing most of their Medicaid pharmacy subrogation claims on paper.

A detailed analysis of the impact on Medicaid agencies and health plans can be found in the proposed rule (73 FR 49779–49781).

In the August 22, 2008 proposed rule (73 FR 49779), we said that the costs for States that currently bill electronically to upgrade their systems to Version 3.0, and to transition from paper Medicaid subrogation claims to using Version 3.0, would be outweighed by the benefits. We did not receive any comments on this conclusion.

1. Impact on States That Use a Contingency Fee Contractor

In the August 22, 2008 proposed rule (73 FR 49779), we said that, for the 33 States that contract out their Medicaid pharmacy subrogation billing processes, there would be no direct costs, and that reimbursement to States would increase proportionally to a projected increase in the volume of electronic claims. The contractors supporting these States

would recover their cost on the back-end, as they would be recouping additional contingency fees based on the volumes. We received no comments on this assumption.

2. Impact on States Converting From Paper

a. Cost of Development

In the August 22, 2008 proposed rule (73 FR 49780), we described the costs that would be incurred by the 14 States converting from a paper process to an electronic process, using Version 3.0, including the cost of development for gap analysis, requirements documentation, training, translator mapping, legacy system changes, acceptance testing and external, end-to-end testing. We said that infrastructure costs would be relatively small, in the range of $50,000 to $150,000 per State, unadjusted for present value. The State would be responsible for 10 percent of those sums, and the Federal government would reimburse the State 90 percent of the design, development, and installation costs related to changes in their Medicaid Management Information Systems (MMIS). We projected that seven States would incur development costs in order to conduct their own billing and the other seven would hire a contingency fee contractor to conduct their billing. We received no comments on these estimates or assumptions.

b. Costs of Adopting and Implementing Trading Partner Agreements (TPAs) With Third Party Payers

In the proposed rule, (73 FR 49780), we said that States would enter into Trading Partner Agreements with other payers in order to conduct subrogation electronically. We projected that approximately forty (40) third party payers, primarily PBMs and claims processors, as well as a few large health plans that process claims in-house, would participate. We stated that trading partner agreements would cost approximately $14,000 to $20,000—with a range of $5,000 to $15,000 for each agreement. We assumed that each State would enter into a trading partner agreement with an average of 15 payers, and that the anticipated costs per State would range from $75,000 to $225,000. As stated in the previous section, we projected that half of the 14 States would hire a contractor, and half would adopt trading partner agreements. Therefore, the agreements with 15 plans would range from $525,000 to $1.6 million, unadjusted for present value. The State would be responsible for 50 percent of the cost since the Federal government reimburses States 50 percent of their administrative costs. We did not receive any comments on this section of the analysis.

3. Impact on States That Bill Electronically (Without a Contractor)

a. Cost of Development

In the August 22, 2008 proposed rule (73 FR 49780), we said that changes for States that bill electronically would be minimal and the cost impact would be much less than for the States that currently bill paper to convert to Version 3.0. We did not receive any comments on this section of the analysis.

b. Costs of Adopting and Implementing Trading Partner Agreements With Third Party Payers

In the August 22, 2008 proposed rule (73 FR 49780), we suggested that the cost to execute and implement trading partner agreements would be approximately $5,000 to $15,000 per agreement, and that four States would establish trading partner agreements with an additional 12 health plans/payers, for a total cost ranging from $20,000 to $60,000, unadjusted for present value. We did not receive any comments on this section of the analysis.

Medicaid Savings

In the August 22, 2008 proposed rule, 73 FR 49780, we stated that the accrued savings to States would outweigh the costs because Medicaid agencies would no longer have to keep track of and use various electronic formats for different payers. We estimated the total number of paper Medicaid pharmacy subrogation claims to be between 2.5 and 3.4 million annually. We cited a study by Milliman in 2006, which was also referenced by the American Medical Association (AMA), which stated that electronic claims can save an average of $3.73 per clean claim. Based on this study, we estimated that the Medicaid program could save an estimated $12.7 million annually unadjusted for present value, once Version 3.0 is fully implemented. We said that the savings represents both State agencies and the Federal government, as the Federal government would share 50 percent of any administrative savings. We did not receive any comments on this section of the analysis.

Impact on Medicaid Pharmacy Providers

In situations where Medicaid has been unable to successfully bill third parties, due to the current challenges of having to use various formats to meet the needs of different payers, States sometimes recoup the subrogation monies from pharmacy providers. We do not believe this practice is widespread and, therefore, did not account for it in the impact analysis. We did not receive any comments on this section of the analysis.

Impact on Third Party Payers (Includes Plan Sponsors, Pharmacy Benefit Managers (PBMs), Prescription Drug Plans (PDPs) and Claims Processors)

1. Impact on Plan Sponsors That Use a PBM or Claim Processor

In the August 22, 2008 proposed rule (73 FR 49781), we stated that the four large PBMs handle about 75 percent of all prescription orders dispensed annually in the United States, and that many of these organizations already accept Version 2.0 subrogation transactions. We said that, for the majority of plan sponsors that contract out their claims adjudication, the costs of implementing Version 3.0 and establishing trading partner agreements would be minimal. We received no comments on this portion of the analysis.

2. Impact on Plan Sponsors That Do Not Use a PBM or Claim Processor

We did not estimate any costs for this sector, as we believe there are few large payers that administer their own claims adjudication. We continue to assume that these payers have already made the necessary investments in developing electronic capabilities to meet HIPAA mandates, and that they will be upgrading their systems in order to accommodate Version D.0, to meet the requirements of this final rule. Since Version 3.0 utilizes a number of the data elements found in Version D.0, we expect additional infrastructure costs to be small. We did not receive any comments on this assumption.

a. Cost of Development

In the August 22, 2008 proposed rule (73 FR 49781), we estimated the development costs to individual health plans that would need to implement Version 3.0 to be similar to the cost for State Medicaid programs, or approximately $50,000 to $150,000. We estimate that there are about 20 payers that do not contract with a PBM and that they would need to upgrade their systems for a total cost of $1 to $3 million, unadjusted for present value. We solicited comments on this subject but received none.

b. Costs of Adopting and Implementing Trading Partner Agreements With States

In the proposed rule (73 FR 49781), we estimated the plan sponsor's costs of adopting and implementing trading partner agreements with States would be similar to the cost estimated for State Medicaid programs, which would range from $5,000 to $15,000 per agreement. We also anticipated that approximately 40 States would utilize a contingency fee contractor, setting up trading partner agreements. We estimated the cost per plan sponsor to range from $60,000 to $180,000, unadjusted for present value, and received no comments on this assumption.

3. Savings Impact

We assumed that 50 percent of all subrogation claims currently require manual review, and that the savings of converting 3.4 million paper claims to electronic transmission would be $3.3 million, unadjusted for present value. We did not receive any comments in the section on savings.

In summary, we did not receive any public comments on the impact analysis for Version 3.0. However, we did receive comments, as described earlier, requesting additional time to implement the standards and expressing the need to implement Version 3.0 either at the same time as, or after, implementation of Version D.0 because of the interdependency of the two standards. The compliance date has been changed to allow for additional implementation time, and to ensure that the Version 3.0 transactions can be used in concert with Version D.0. Based on the adopted effective and compliance dates, we have revised the tables to coincide with the new dates.

Summary of Costs and Benefits for This Final Rule

The final tables, 4a and 4b, which replace tables 14a and 14b from the proposed rule, are the compilation of the total low and high costs and benefits for all of the standards being adopted in this final rule. In the proposed rule, we did not adjust for present value. In order to assure readers a valid comparison, we also did not adjust for present value in the final rule in the main text of the document. However, for the reader's edification, in Tables 4a and 4b, we show the costs and benefits discounted by 7% and 3% to reflect present value.

TABLE 4A—ESTIMATED LOW AND HIGH COSTS—IN MILLIONS*—FOR YEARS 2009 THROUGH 2019 FOR IMPLEMENTATION OF VERSIONS 5010, D.0 AND 3.0

| Cost type | Industry | Unadjusted for present value | @ 3% Discount | @ 7% Discount |
|---|---|---|---|---|
| 5010—Imp costs | Hospitals—low | $792 | $762 | $727 |
| | Hospitals—high | 1,584 | 1,525 | 1,453 |
| | Physicians—low | 370 | 356 | 339 |
| | Physicians—high | 740 | 712 | 679 |
| | Dentists—low | 254 | 245 | 233 |
| | Dentists—high | 508 | 489 | 466 |
| | pharmacy—low | 57 | 55 | 52 |
| | pharmacy—high | 114 | 110 | 105 |
| | private hp—low | 3,063 | 2,949 | 2,810 |
| | private hp—high | 6,127 | 5,898 | 5,621 |
| | govt hp—low | 213 | 205 | 195 |
| | govt hp—high | 410 | 395 | 376 |
| | CH—low | 137 | 132 | 126 |
| | CH—high | 167 | 161 | 153 |
| 5010 Transition costs | Hospitals—low | 373 | 338 | 298 |
| | Hospitals—high | 746 | 677 | 597 |
| | Physicians—low | 174 | 158 | 139 |
| | Physicians—high | 348 | 316 | 279 |
| | Dentists—low | 120 | 109 | 96 |
| | Dentists—high | 239 | 217 | 191 |
| | pharmacy—low | 27 | 24 | 22 |
| | pharmacy—high | 54 | 49 | 43 |
| | private hp—low | 1,442 | 1,308 | 1,154 |
| | private hp—high | 2,883 | 2,615 | 2,307 |
| | govt hp—low | 100 | 91 | 80 |
| | govt hp—high | 193 | 175 | 154 |
| | CH—low | 24 | 22 | 19 |
| | CH—high | 30 | 27 | 24 |
| Medicaid subrogation development | federal—low | .32 | .29 | .27 |
| | federal—high | .94 | .87 | .79 |
| | state—low | .040 | .037 | .034 |
| | state—high | .1 | .093 | .084 |
| | payers—low | 1 | .93 | .844 |
| | payers—high | 3 | 2.78 | 2.53 |
| Medicaid subrogation—Trading Partner agreements. | federal—low | .38 | .35 | .32 |
| | federal—high | 1.16 | 1.07 | .98 |
| | state—low | .38 | .35 | .32 |
| | state—high | 1.16 | 1.07 | .98 |
| | payers—low | 2.4 | 2.2 | 2 |
| | payers—high | 7 | 7 | 6 |
| D.0—pharmacy chain systems implementation | pharmacy—low | 18 | 17 | 16 |
| | pharmacy—high | 38 | 36 | 34 |
| Independent pharmacy maintenance fees | pharmacy—low | .54 | .51 | .48 |
| | pharmacy—high | 1.08 | 1.03 | .97 |

TABLE 4A—ESTIMATED LOW AND HIGH COSTS—IN MILLIONS*—FOR YEARS 2009 THROUGH 2019 FOR IMPLEMENTATION OF VERSIONS 5010, D.0 AND 3.0—Continued

| Cost type | Industry | Unadjusted for present value | @ 3% Discount | @ 7% Discount |
|---|---|---|---|---|
| PBM programming | PBM—low | 8 | 8 | 7 |
| | PBM—high | 10 | 9.5 | 9 |
| Total Costs | LOW | 7,177 | 6,783 | 6,319 |
| Total Costs | HIGH | 14,206 | 13,425 | 12,505 |

TABLE 4B—ESTIMATED LOW AND HIGH BENEFITS—IN MILLIONS*—FOR YEARS 2009 THROUGH 2019 FOR IMPLEMENTATION OF VERSIONS 5010, D.0 AND 3.0

| Savings type | Industry | Unadjusted for present value | @ 3% Discount | @ 7% Discount |
|---|---|---|---|---|
| 5010 operational savings | Hospitals—low | $348 | $286 | $224 |
| | Hospitals—high | 952 | 783 | 612 |
| | Physicians—low | 1,392 | 1,144 | 895 |
| | Physicians—high | 3,802 | 3,126 | 2,445 |
| | Dentists—low | 237 | 195 | 153 |
| | Dentists—high | 605 | 497 | 389 |
| | pharmacy—low | 16 | 13 | 10 |
| | pharmacy—high | 23 | 19 | 15 |
| | private and govt hp—low | 1,330 | 1,093 | 855 |
| | private and govt hp—high | 3,577 | 2,941 | 2,300 |
| | CH—low | 0 | 0 | 0 |
| | CH—high | 0 | 0 | 0 |
| 5010 cost savings increase in transactions | Hospitals—low | 66 | 53 | 40 |
| | Hospitals—high | 219 | 176 | 133 |
| | Physicians—low | 270 | 217 | 164 |
| | Physicians—high | 874 | 702 | 532 |
| | Dentists—low | 45 | 36 | 27 |
| | Dentists—high | 56 | 45 | 34 |
| | pharmacy—low | 0 | 0 | 0 |
| | pharmacy—high | 0 | 0 | 0 |
| | private and govt hp—low | 135 | 110 | 86 |
| | private and govt hp—high | 338 | 276 | 214 |
| | CH—low | 0 | 0 | 0 |
| | CH—high | 0 | 0 | 0 |
| 5010 operational savings—increase in auxiliary claim transaction. | Hospitals—low | 1,131 | 897 | 669 |
| | Hospitals—high | 2,890 | 2,288 | 1,700 |
| | Physicians—low | 4,442 | 3,517 | 2,612 |
| | Physicians—high | 11,553 | 9,147 | 6,795 |
| | Dentists—low | 752 | 595 | 442 |
| | Dentists—high | 1,839 | 1,456 | 1,082 |
| | pharmacy—low | 0 | 0 | 0 |
| | pharmacy—high | 0 | 0 | 0 |
| | private and govt hp—low | 4,519 | 3,578 | 2,658 |
| | private and govt hp—high | 11,749 | 9,302 | 6,910 |
| | CH—low | 0 | 0 | 0 |
| | CH—high | 0 | 0 | 0 |
| Medicaid subrogation | fed—low | 13 | 11 | 10 |
| | fed—high | 18 | 16 | 13 |
| | state—low | 13 | 11 | 10 |
| | state—high | 18 | 16 | 13 |
| | payer—low | 7 | 6 | 5 |
| | payer—high | 9 | 8 | 7 |
| Version D.0 | Pharmacist productivity—low | 951 | 779 | 607 |
| | Pharmacist productivity—high | 1,921 | 1,574 | 1,225 |
| Version D.0 | Pharmacy technician productivity—low | 77 | 63 | 49 |
| | Pharmacy technician productivity—high | 160 | 132 | 103 |
| Version D.0 | Avoided audits—low | 152 | 126 | 99 |
| | Avoided audits—high | 304 | 251 | 198 |
| Total Benefits | LOW | 15,896 | 12,732 | 9,615 |
| Total Benefits | HIGH | 40,906 | 32,753 | 24,719 |

Accounting Statement and Table

Whenever a rule is considered a significant rule under Executive Order 12866, we are required to develop an Accounting Statement. This statement must state that we have prepared an accounting statement showing the classification of the expenditures associated with the provisions of this final rule. Monetary annualized Benefits and non-budgetary costs are presented as discounted flows using three percent and seven percent factors.

TABLE 5—ACCOUNTING STATEMENT

[Accounting statement: classification of estimated expenditures, from FY2009 to FY2019 (in millions)]

| Category | Primary estimate (millions) | Minimum estimate (millions) | Maximum estimate (millions) | Source citation (RIA, preamble, etc.) |
|---|---|---|---|---|
| BENEFITS: | | | | |
| Annualized Monetized benefits: | | | | |
| 7% Discount | 2,142.4 | 1,203.7 | 3,081.1 | RIA |
| 3% Discount | 2,389.5 | 1,314.8 | 3,437.2 | RIA |
| Qualitative (un-quantified) benefits | Wider adoption of standards due to decrease in use of companion guides; increased productivity due to decrease in manual intervention requirements. | | | |
| Benefits generated from plans to providers and pharmacies, providers to plans and pharmacies, and pharmacies to beneficiaries. | | | | |
| COSTS: | | | | |
| Annualized Monetized costs: | | | | |
| 7% Discount | 1,144.0 | 787.5 | 1,500.5 | RIA |
| 3% Discount | 1,034.8 | 711.7 | 1,357.8 | RIA |
| Qualitative (un-quantified) costs | None | None | None | |
| Cost will be paid by health plans to contractors, programming consultants, IT staff and other outsourced entities; providers will pay costs to software vendors, trainers and other consultants. Clearinghouses will pay costs to IT staff/contractors and software developers; pharmacies will pay costs to contractors, software vendors and trainers, and government plans will pay costs to consultants, vendors and staff. | | | | |
| TRANSFERS: | | | | |
| Annualized monetized transfers: "on budget" | N/A | N/A | N/A | |
| From whom to whom? | N/A | N/A | N/A | |
| Annualized monetized transfers: "off-budget" | N/A | N/A | N/A | |
| From whom to whom? | N/A | N/A | N/A | |

In accordance with the provisions of Executive Order 12866, as amended, this regulation was reviewed by the Office of Management and Budget.

**List of Subjects in 45 CFR Part 162**

Administrative practice and procedure, Electronic transactions, Health facilities, Health insurance, Hospitals, Incorporation by reference, Medicare, Medicaid, Reporting and recordkeeping requirements.

■ For the reasons set forth in the preamble, the Department of Health and Human Services amends 45 CFR Part 162 as set forth below:

## PART 162—ADMINISTRATIVE REQUIREMENTS

■ 1. The authority citation for part 162 is revised to read as follows:

**Authority:** Secs. 1171 through 1180 of the Social Security Act (42 U.S.C.1320d–1320d–9), as added by sec. 262 of Pub. L. 104–191, 110 Stat. 2021–2031, and sec. 105 of Public Law 110–233, 122 Stat. 881–922, and sec. 264 of Pub. L. 104–191, 110 Stat. 2033–2034 (42 U.S.C. 1320d–2 (note)).

### Subpart A—General Provisions

■ 2. Amend § 162.103 by revising the definition of ''standard transaction'' to read as follows:

**§ 162.103 Definitions.**

* * * * *

*Standard transaction* means a transaction that complies with an applicable standard adopted under this part.

### Subpart I—General Provisions for Transactions

**§ 162.900 [Removed and Reserved]**

■ 3. Remove and reserve § 162.900.

■ 4. Amend § 162.920 as follows:

■ A. Revise introductory text and paragraph (a) introductory text.

■ B. Add paragraphs (a)(10) through (a)(18).

■ C. Revise paragraph (b) introductory text.

■ D. Add paragraphs (b)(4) through (b)(6).

The revisions and additions read as follows:

**§ 162.920 Availability of implementation specifications.**

A person or an organization may directly request copies of the implementation specifications and the Technical Reports Type 3 described in subparts I through S of this part from the publishers listed in this section. The Director of the Federal Register approves the implementation specifications, which include the Technical Reports Type 3 described in this section, for incorporation by reference in subparts I through S of this part in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The implementation specifications and Technical Reports Type 3 described in this section are also available for inspection by the public at the Centers for Medicare & Medicaid Services (CMS), 7500 Security Boulevard, Baltimore, Maryland 21244. For more information on the availability on the materials at CMS, call (410) 786–6597. The implementation specifications and Technical Reports Type 3 are also available at the National Archives and Records Administration (NARA). For information on the

availability of this material at NARA, call (202) 714–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html*. Implementation specifications are available for the following transactions.

(a) *ASC X12N specifications and the ASC X12 Standards for Electronic Data Interchange Technical Report Type 3.* The implementation specifications for the ASC X12N and the ASC X12 Standards for Electronic Data Interchange Technical Report Type 3 (and accompanying Errata or Type 1 Errata) may be obtained from the ASC X12, 7600 Leesburg Pike, Suite 430, Falls Church, VA 22043; Telephone (703) 970–4480; and FAX (703) 970–4488. They are also available through the internet at *http://www.X12.org*. A fee is charged for all implementation specifications, including Technical Reports Type 3. Charging for such publications is consistent with the policies of other publishers of standards. The transaction implementation specifications are as follows:

* * * * *

(10) The ASC X12 Standards for Electronic Data Interchange Technical Report Type 3—Health Care Claim: Dental (837), May 2006, ASC X12N/005010X224, and Type 1 Errata to Health Care Claim Dental (837), ASC X12 Standards for Electronic Data Interchange Technical Report Type 3, October 2007, ASC X12N/005010X224A1, as referenced in § 162.1102 and § 162.1802.

(11) The ASC X12 Standards for Electronic Data Interchange Technical Report Type 3—Health Care Claim: Professional (837), May 2006, ASC X12, 005010X222, as referenced in § 162.1102 and § 162.1802.

(12) The ASC X12 Standards for Electronic Data Interchange Technical Report Type 3—Health Care Claim: Institutional (837), May 2006, ASC X12/N005010X223, and Type 1 Errata to Health Care Claim: Institutional (837), ASC X12 Standards for Electronic Data Interchange Technical Report Type 3, October 2007, ASC X12N/005010X223A1, as referenced in § 162.1102 and § 162.1802.

(13) The ASC X12 Standards for Electronic Data Interchange Technical Report Type 3—Health Care Claim Payment/Advice (835), April 2006, ASC X12N/005010X221, as referenced in § 162.1602.

(14) The ASC X12 Standards for Electronic Data Interchange Technical Report Type 3—Benefit Enrollment and Maintenance (834), August 2006, ASC X12N/005010X220, as referenced in § 162.1502.

(15) The ASC X12 Standards for Electronic Data Interchange Technical Report Type 3—Payroll Deducted and Other Group Premium Payment for Insurance Products (820), February 2007, ASC X12N/005010X218, as referenced in § 162.1702.

(16) The ASC X12 Standards for Electronic Data Interchange Technical Report Type 3—Health Care Services Review—Request for Review and Response (278), May 2006, ASC X12N/005010X217, and Errata to Health Care Services Review—Request for Review and Response (278), ASC X12 Standards for Electronic Data Interchange Technical Report Type 3, April 2008, ASC X12N/005010X217E1, as referenced in § 162.1302.

(17) The ASC X12 Standards for Electronic Data Interchange Technical Report Type 3—Health Care Claim Status Request and Response (276/277), August 2006, ASC X12N/005010X212, and Errata to Health Care Claim Status Request and Response (276/277), ASC X12 Standards for Electronic Data Interchange Technical Report Type 3, April 2008, ASC X12N/005010X212E1, as referenced in § 162.1402.

(18) The ASC X12 Standards for Electronic Data Interchange Technical Report Type 3—Health Care Eligibility Benefit Inquiry and Response (270/271), April 2008, ASC X12N/005010X279, as referenced in § 162.1202.

(b) *Retail pharmacy specifications and Medicaid subrogation implementation guides.* The implementation specifications for the retail pharmacy standards and the implementation specifications for the batch standard for the Medicaid pharmacy subrogation transaction may be obtained from the National Council for Prescription Drug Programs, 9240 East Raintree Drive, Scottsdale, AZ 85260. Telephone (480) 477–1000; FAX (480) 767–1042. They are also available through the Internet at *http://www.ncpdp.org*. A fee is charged for all NCPDP Implementation Guides. Charging for such publications is consistent with the policies of other publishers of standards. The transaction implementation specifications are as follows:

* * * * *

(4) The Telecommunication Standard Implementation Guide, Version D, Release 0 (Version D.0), August 2007, National Council for Prescription Drug Programs, as referenced in § 162.1102, § 162.1202, § 162.1302, and § 162.1802.

(5) The Batch Standard Implementation Guide, Version 1, Release 2 (Version 1.2), January 2006, National Council for Prescription Drug Programs, as referenced in § 162.1102, § 162.1202, § 162.1302, and § 162.1802.

(6) The Batch Standard Medicaid Subrogation Implementation Guide, Version 3, Release 0 (Version 3.0), July 2007, National Council for Prescription Drug Programs, as referenced in § 162.1902.

■ 5. Revise § 162.923 paragraph (a) to read as follows:

**§ 162.923 Requirements for covered entities.**

(a) *General rule.* Except as otherwise provided in this part, if a covered entity conducts, with another covered entity that is required to comply with a transaction standard adopted under this part (or within the same covered entity), using electronic media, a transaction for which the Secretary has adopted a standard under this part, the covered entity must conduct the transaction as a standard transaction.

* * * * *

■ 6. Section 162.925 is amended by adding a new paragraph (a)(6) to read as follows:

**§ 162.925 Additional requirements for health plans.**

(a) * * *

(6) During the period from March 17, 2009 through December 31, 2011, a health plan may not delay or reject a standard transaction, or attempt to adversely affect the other entity or the transaction, on the basis that it does not comply with another adopted standard for the same period.

* * * * *

## Subpart K—Health Care Claims or Equivalent Encounter Information

■ 7. Amend § 162.1102 by—

■ A. Removing paragraph (a).

■ B. Redesignating existing paragraph (b) as paragraph (a).

■ C. Revising the introductory text of newly redesignated paragraph (a).

■ D. Adding new paragraphs (b) and (c).

The revisions and additions read as follows:

**§ 162.1102 Standards for health care claims or equivalent encounter information transaction.**

* * * * *

(a) For the period from October 16, 2003 through March 16, 2009:

* * * * *

(b) For the period from March 17, 2009 through December 31, 2011, both:

(1)(i) The standards identified in paragraph (a) of this section; and

(ii) For retail pharmacy supplies and professional services claims, the

following: The ASC X12N 837—Health Care Claim: Professional, Volumes 1 and 2, Version 4010, May 2000, Washington Publishing Company, 004010X096, October 2002 (Incorporated by reference in § 162.920); and

(2)(i) *Retail pharmacy drug claims.* The Telecommunication Standard Implementation Guide, Version D, Release 0 (Version D.0), August 2007 and equivalent Batch Standard Implementation Guide, Version 1, Release 2 (Version 1.2), National Council for Prescription Drug Programs. (Incorporated by reference in § 162.920.)

(ii) *Dental health care claims.* The ASC X12 Standards for Electronic Data Interchange Technical Report Type 3—Health Care Claim: Dental (837), May 2006, ASC X12N/005010X224, and Type 1 Errata to Health Care Claim: Dental (837) ASC X12 Standards for Electronic Date Interchange Technical Report Type 3, October 2007, ASC X12N/005010X224A1. (Incorporated by reference in § 162.920.)

(iii) *Professional health care claims.* The ASC X12 Standards for Electronic Data Interchange Technical Report Type 3—Health Care Claim: Professional (837), May 2006, ASC X12N/005010X222. (Incorporated by reference in § 162.920.)

(iv) *Institutional health care claims.* The ASC X12 Standards for Electronic Data Interchange Technical Report Type 3—Health Care Claim: Institutional (837), May 2006, ASC X12N/005010X223, and Type 1 Errata to Health Care Claim: Institutional (837) ASC X12 Standards for Electronic Data Interchange Technical Report Type 3, October 2007, ASC X12N/005010X223A1. (Incorporated by reference in § 162.920.)

(v) *Retail pharmacy supplies and professional services claims.* (A) The Telecommunication Standard, Implementation Guide Version 5, Release 1, September 1999. (Incorporated by reference in § 162.920.)

(B) The Telecommunication Standard Implementation Guide, Version D, Release 0 (Version D.0), August 2007, and equivalent Batch Standard Implementation Guide, Version 1, Release 2 (Version 1.2), National Council for Prescription Drug Programs (Incorporated by reference in § 162.920); and

(C) The ASC X12 Standards for Electronic Data Interchange Technical Report Type 3—Health Care Claim: Professional (837), May 2006, ASC X12N/005010X222. (Incorporated by reference in § 162.920.)

(c) For the period on and after the January 1, 2012, the standards identified in paragraph (b)(2) of this section, except the standard identified in paragraph (b)(2)(v)(A) of this section.

## Subpart L—Eligibility for a Health Plan

■ 8. Section 162.1202 is amended by—
■ A. Removing paragraph (a).
■ B. Redesignating existing paragraph (b) as paragraph (a).
■ C. Revising the introductory text of newly redesignated paragraph (a).
■ D. Adding new paragraphs (b) and (c).

The revisions and additions read as follows:

### § 162.1202 Standards for eligibility for a health plan transaction.

* * * * *

(a) For the period from October 16, 2003 through March 16, 2009:

* * * * *

(b) For the period from March 17, 2009 through December 31, 2011 both:

(1) The standards identified in paragraph (a) of this section; and

(2) (i) *Retail pharmacy drugs.* The Telecommunication Standard Implementation Guide Version D, Release 0 (Version D.0), August 2007, and equivalent Batch Standard Implementation Guide, Version 1, Release 2 (Version 1.2), National Council for Prescription Drug Programs. (Incorporated by reference in § 162.920.)

(ii) *Dental, professional, and institutional health care eligibility benefit inquiry and response.* The ASC X12 Standards for Electronic Data Interchange Technical Report Type 3—Health Care Eligibility Benefit Inquiry and Response (270/271), April 2008, ASC X12N/005010X279. (Incorporated by reference in § 162.920.)

(c) For the period on and after January 1, 2012, the standards identified in paragraph (b)(2) of this section.

## Subpart M—Referral Certification and Authorization

■ 9. Revise § 162.1301 to read as follows:

### § 162.1301 Referral certification and authorization transaction.

The referral certification and authorization transaction is any of the following transmissions:

(a) A request from a health care provider to a health plan for the review of health care to obtain an authorization for the health care.

(b) A request from a health care provider to a health plan to obtain authorization for referring an individual to another health care provider.

(c) A response from a health plan to a health care provider to a request described in paragraph (a) or paragraph (b) of this section.

■ 10. Section 162.1302 is amended by—
■ A. Removing paragraph (a).
■ B. Redesignating existing paragraph (b) as paragraph (a).
■ C. Revising the introductory text of newly redesignated paragraph (a).
■ D. Adding new paragraphs (b) and (c).

The revisions and additions read as follows:

### § 162.1302 Standards for referral certification and authorization transaction.

* * * * *

(a) For the period from October 16, 2003 through March 16, 2009:

* * * * *

(b) For the period from March 17, 2009 through December 31, 2011 both—

(1) The standards identified in paragraph (a) of this section; and

(2)(i) *Retail pharmacy drugs.* The Telecommunication Standard Implementation Guide Version D, Release 0 (Version D.0), August 2007, and equivalent Batch Standard Implementation Guide, Version 1, Release 2 (Version 1.2), National Council for Prescription Drug Programs. (Incorporated by reference in § 162.920.)

(ii) *Dental, professional, and institutional request for review and response.* The ASC X12 Standards for Electronic Data Interchange Technical Report Type 3—Health Care Services Review—Request for Review and Response (278), May 2006, ASC X12N/005010X217, and Errata to Health Care Services Review-—Request for Review and Response (278), ASC X12 Standards for Electronic Data Interchange Technical Report Type 3, April 2008, ASC X12N/005010X217E1. (Incorporated by reference in § 162.920.)

(c) For the period on and after January 1, 2012, the standards identified in paragraph (b)(2) of this section.

## Subpart N—Health Care Claim Status

■ 11. Revise § 162.1401 to read as follows:

### § 162.1401 Health care claim status transaction.

The health care claim status transaction is the transmission of either of the following:

(a) An inquiry from a health care provider to a health plan to determine the status of a health care claim.

(b) A response from a health plan to a health care provider about the status of a health care claim.

■ 12. Section 162.1402 is revised to read as follows:

### § 162.1402 Standards for health care claim status transaction.

The Secretary adopts the following standards for the health care claim status transaction:

(a) For the period from October 16, 2003 through March 16, 2009: The ASC X12N–276/277 Health Care Claim Status Request and Response, Version 4010, May 2000, Washington Publishing Company, 004010X093 and Addenda to Health Care Claim Status Request and Response, Version 4010, October 2002, Washington Publishing Company, 004010X093A1. (Incorporated by reference in § 162.920.)

(b) For the period from March 17, 2009 through December 31, 2011, both:

(1) The standard identified in paragraph (a) of this section; and

(2) The ASC X12 Standards for Electronic Data Interchange Technical Report Type 3—Health Care Claim Status Request and Response (276/277), August 2006, ASC X12N/005010X212, and Errata to Health Care Claim Status Request and Response (276/277), ASC X12 Standards for Electronic Data Interchange Technical Report Type 3, April 2008, ASC X12N/005010X212E1. (Incorporated by reference in § 162.920.)

(c) For the period on and after January 1, 2012, the standard identified in paragraph (b)(2) of this section.

## Subpart O—Enrollment and Disenrollment in a Health Plan

13. Revise § 162.1501 to read as follows:

### § 162.1501 Enrollment and disenrollment in a health plan transaction.

The enrollment and disenrollment in a health plan transaction is the transmission of subscriber enrollment information from the sponsor of the insurance coverage, benefits, or policy, to a health plan to establish or terminate insurance coverage.

■ 14. Section 162.1502 is revised to read as follows:

### § 162.1502 Standards for enrollment and disenrollment in a health plan transaction.

The Secretary adopts the following standards for enrollment and disenrollment in a health plan transaction.

(a) For the period from October 16, 2003 through March 16, 2009: ASC X12N 834—Benefit Enrollment and Maintenance, Version 4010, May 2000, Washington Publishing Company, 004010X095 and Addenda to Benefit Enrollment and Maintenance, Version 4010, October 2002, Washington Publishing Company, 004010X095A1. (Incorporated by reference in § 162.920.)

(b) For the period from March 17, 2009 through December 31, 2011, both:

(1) The standard identified in paragraph (a) of this section; and

(2) The ASC X12 Standards for Electronic Data Interchange Technical Report Type 3—Benefit Enrollment and Maintenance (834), August 2006, ASC X12N/005010X220 (Incorporated by reference in § 162.920)

(c) For the period on and after January 1, 2012, the standard identified in paragraph (b)(2) of this section.

## Subpart P—Health Care Payment and Remittance Advice

■ 15. Section 162.1602 is revised to read as follows:

### § 162.1602 Standards for health care payment and remittance advice transaction:

The Secretary adopts the following standards for the health care payment and remittance advice transaction:

(a) For the period from October 16, 2003 through March 16, 2009: Health care claims and remittance advice. The ASC X12N 835—Health Care Claim Payment/Advice, Version 4010, May 2000, Washington Publishing Company, 004010X091, and Addenda to Health Care Claim Payment/Advice, Version 4010, October 2002, Washington Publishing Company, 004010X091A1. (Incorporated by reference in § 162.920.)

(b) For the period from March 17, 2009 through December 31, 2011, both:

(1) The standard identified in paragraph (a) of this section; and

(2) The ASC X12 Standards for Electronic Data Interchange Technical Report Type 3—Health Care Claim Payment/Advice (835), April 2006, ASC X12N/005010X221. (Incorporated by reference in § 162.920.)

(c) For the period on and after January 1, 2012, the standard identified in paragraph (b)(2) of this section.

## Subpart Q—Health Plan Premium Payments

■ 16. Section 162.1702 is revised to read as follows:

### § 162.1702 Standards for health plan premium payments transaction.

The Secretary adopts the following standards for the health plan premium payments transaction:

(a) For the period from October 16, 2003 through March 16, 2009: The ASC X12N 820—Payroll Deducted and Other Group Premium Payment for Insurance Products, Version 4010, May 2000, Washington Publishing Company, 004010X061, and Addenda to Payroll Deducted and Other Group Premium Payment for Insurance Products, Version 4010, October 2002, Washington Publishing Company, 004010X061A1. (Incorporated by reference in § 162.920.)

(b) For the period from March 17, 2009 through December 31, 2011, both:

(1) The standard identified in paragraph (a) of this section, and

(2) The ASC X12 Standards for Electronic Data Interchange Technical Report Type 3—Payroll Deducted and Other Group Premium Payment for Insurance Products (820), February 2007, ASC X12N/005010X218. (Incorporated by reference in § 162.920.)

(c) For the period on and after January 1, 2012, the standard identified in paragraph (b)(2) of this section.

## Subpart R—Coordination of Benefits

■ 17. Section 162.1802 is amended by—

■ A. Removing paragraph (a).

■ B. Redesignating existing paragraph (b) as paragraph (a).

■ C. Revising the introductory text of newly redesignated paragraph (a).

■ D. Adding new paragraphs (b) and (c).

The additions and revisions read as follows:

### § 162.1802 Standards for coordination of benefits information transaction.

* * * * *

(a) For the period from October 16, 2003 through March 16, 2009:

* * * * *

(b) For the period from March 17, 2009 through December 31, 2011, both:

(1) The standards identified in paragraph (a) of this section; and

(2)(i) *Retail pharmacy drug claims.* The Telecommunication Standard Implementation Guide, Version D, Release 0 (Version D.0), August 2007, and equivalent Batch Standard Implementation Guide, Version 1, Release 2 (Version 1.2), National Council for Prescription Drug Programs. (Incorporated by reference in § 162.920.)

(ii) The ASC X12 Standards for Electronic Data Interchange Technical Report Type 3—Health Care Claim: Dental (837), May 2006, ASC X12N/005010X224, and Type 1 Errata to Health Care Claim: Dental (837), ASC X12 Standards for Electronic Date Interchange Technical Report Type 3, October 2007, ASC X12N/005010X224A1. (Incorporated by reference in § 162.920.)

(iii) The ASC X12 Standards for Electronic Data Interchange Technical Report Type 3—Health Care Claim: Professional (837), May 2006, ASC X12N/005010X222. (Incorporated by reference in § 162.920.)

(iv) The ASC X12 Standards for Electronic Data Interchange Technical Report Type 3—Health Care Claim: Institutional (837), May 2006, ASC X12N/005010X223, and Type 1 Errata to Health Care Claim: Institutional (837), ASC X12 Standards for Electronic Data Interchange Technical Report Type 3,

October 2007, ASC X12N/005010X223A1. (Incorporated by reference in § 162.920.)

(c) For the period on and after January 1, 2012, the standards identified in paragraph (b)(2) of this section.

■ 18. Add a new Subpart S to read as follows:

## Subpart S—Medicaid Pharmacy Subrogation

Sec.
162.1901 Medicaid pharmacy subrogation transaction.
162.1902 Standard for Medicaid pharmacy subrogation transaction.

### § 162.1901 Medicaid pharmacy subrogation transaction.

The Medicaid pharmacy subrogation transaction is the transmission of a claim from a Medicaid agency to a payer for the purpose of seeking reimbursement from the responsible health plan for a pharmacy claim the State has paid on behalf of a Medicaid recipient.

### § 162.1902 Standard for Medicaid pharmacy subrogation transaction.

The Secretary adopts the Batch Standard Medicaid Subrogation Implementation Guide, Version 3, Release 0 (Version 3.0), July 2007, National Council for Prescription Drug Programs, as referenced in § 162.1902 (Incorporated by reference at § 162.920):

(a) For the period on and after January 1, 2012, for covered entities that are not small health plans;

(b) For the period on and after January 1, 2013 for small health plans.

(Catalog of Federal Domestic Assistance Program No. 93.778, Medical Assistance Program) (Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance; and Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Approved: December 11, 2008.

**Michael O. Leavitt,**

*Secretary.*

[FR Doc. E9–740 Filed 1–15–09; 8:45 am]

BILLING CODE 4150–28–P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Office of the Secretary

### 45 CFR Part 162

**[CMS–0013–F]**

**RIN 0958–AN25**

## HIPAA Administrative Simplification: Modifications to Medical Data Code Set Standards To Adopt ICD–10–CM and ICD–10–PCS

**AGENCY:** Office of the Secretary, HHS.

**ACTION:** Final rule.

**SUMMARY:** This final rule adopts modifications to two of the code set standards adopted in the Transactions and Code Sets final rule published in the **Federal Register** pursuant to certain provisions of the Administrative Simplification subtitle of the Health Insurance Portability and Accountability Act of 1996 (HIPAA). Specifically, this final rule modifies the standard medical data code sets (hereinafter ''code sets'') for coding diagnoses and inpatient hospital procedures by concurrently adopting the International Classification of Diseases, 10th Revision, Clinical Modification (ICD–10–CM) for diagnosis coding, including the Official ICD–10–CM Guidelines for Coding and Reporting, as maintained and distributed by the U.S. Department of Health and Human Services (HHS), hereinafter referred to as ICD–10–CM, and the International Classification of Diseases, 10th Revision, Procedure Coding System (ICD–10–PCS) for inpatient hospital procedure coding, including the Official ICD–10–PCS Guidelines for Coding and Reporting, as maintained and distributed by the HHS, hereinafter referred to as ICD–10–PCS. These new codes replace the International Classification of Diseases, 9th Revision, Clinical Modification, Volumes 1 and 2, including the Official ICD–9–CM Guidelines for Coding and Reporting, hereinafter referred to as ICD–9–CM Volumes 1 and 2, and the International Classification of Diseases, 9th Revision, Clinical Modification, Volume 3, including the Official ICD–9–CM Guidelines for Coding and Reporting, hereinafter referred to as ICD–9–CM Volume 3, for diagnosis and procedure codes, respectively.

**DATES:** The effective date of this regulation is March 17, 2009. The effective date is the date that the policies herein take effect, and new policies are considered to be officially adopted. The compliance date, which is different than the effective date, is the date on which entities are required to have implemented the policies adopted in this rule. The compliance date for this regulation is October 1, 2013.

**FOR FURTHER INFORMATION CONTACT:** Denise M. Buenning, (410) 786–6711 or Shannon L. Metzler, (410) 786–3267.

## I. Background

### *A. Statutory Background*

The Congress addressed the need for a consistent framework for electronic transactions and other administrative simplification issues in the Health Insurance Portability and Accountability Act of 1996 (HIPAA), Public Law 104–191, enacted on August 21, 1996. HIPAA has helped to improve the Medicare and Medicaid programs, and the efficiency and effectiveness of the health care system in general, by encouraging the development of standards and requirements to facilitate the electronic transmission of certain health information.

Through subtitle F of title II of that statute, the Congress added to title XI of the Social Security Act (the Act) a new Part C, titled ''Administrative Simplification.'' Part C of title XI of the Act now consists of sections 1171 through 1180. Section 1172 of the Act and the implementing regulations make any standard adopted under Part C applicable to: (1) Health plans; (2) health care clearinghouses; and (3) health care providers who transmit any health information in electronic form in connection with a transaction for which the Secretary has adopted a standard.

Section 1172(c)(1) of the Act requires any standard adopted by the Secretary of the Department of Health and Human Services (HHS) to be developed, adopted, or modified by a standard setting organization (SSO), except in the cases identified under section 1172(c)(2) of the Act. Under section 1172(c)(2)(A) of the Act, the Secretary may adopt a standard that is different from any standard developed by an SSO if it will substantially reduce administrative costs to health care providers and health plans compared to the alternatives, and the standard is promulgated in accordance with the rulemaking procedures of subchapter III of chapter 5 of Title 5 of the United States Code. Under section 1172(c)(2)(B) of the Act, if no SSO has developed, adopted, or modified any standard relating to a standard that the Secretary is authorized or required to adopt, section 1172(c)(1) does not apply.

Section 1172 of the Act also sets forth consultation requirements that must be met before the Secretary may adopt

**Blue Cross Blue Shield of Delaware**
**Stand Alone Basis - Five Year Forecast (2011 Through 2015) - Current Version**
**August 10, 2011**

| | Forecast | | | | | |
|---|---|---|---|---|---|---|
| | 2010 | 2011 | 2012 | 2013 | 2014 | 2015 |
| Contract Months | | | | | | |
| Individual < 65 | 70,970 | 62,507 | 59,025 | 57,254 | 60,429 | 62,755 |
| Individual > 65 | 42,232 | 41,002 | 40,432 | 39,219 | 38,043 | 36,901 |
| Small Group | 198,509 | 192,504 | 189,920 | 184,083 | 161,065 | 141,376 |
| Large Group | 303,278 | 306,242 | 303,953 | 280,463 | 262,733 | 254,851 |
| Self-Funded | 1,189,430 | 1,151,264 | 1,108,460 | 1,075,778 | 1,045,603 | 1,000,650 |
| FEP | 116,946 | 118,491 | 118,800 | 118,800 | 118,800 | 118,800 |
| Medicaid | - | - | - | - | - | - |
| Non-Risk Par | 622,484 | 648,540 | 650,232 | 650,232 | 650,232 | 650,232 |
| Total | 2,543,849 | 2,520,550 | 2,470,822 | 2,405,829 | 2,336,904 | 2,265,566 |
| Member Months | | | | | | |
| Individual < 65 | 111,427 | 99,459 | 94,034 | 91,213 | 99,707 | 103,546 |
| Individual > 65 | 42,232 | 41,002 | 40,432 | 39,219 | 38,043 | 36,901 |
| Small Group | 375,731 | 365,471 | 360,338 | 349,264 | 305,591 | 268,235 |
| Large Group | 587,291 | 595,628 | 592,664 | 546,862 | 512,293 | 496,924 |
| Self-Funded | 2,274,108 | 2,201,381 | 2,119,706 | 2,057,208 | 1,999,504 | 1,913,541 |
| FEP | 216,411 | 224,386 | 225,607 | 225,607 | 225,607 | 225,607 |
| Medicaid | - | | - | - | - | - |
| Non-Risk Par | 1,171,616 | 1,224,418 | 1,227,320 | 1,227,320 | 1,227,320 | 1,227,320 |
| Total | 4,778,816 | 4,751,745 | 4,660,101 | 4,536,693 | 4,408,065 | 4,272,074 |
| Revenue | 146,860,999 | 149,186,953 | 153,710,763 | 155,691,294 | 142,353,239 | 130,574,548 |
| Individual < 65 | 30,179,497 | 27,357,738 | 28,322,731 | 30,082,996 | 36,008,424 | 40,947,360 |
| Individual > 65 | 9,605,173 | 9,034,940 | 9,354,805 | 9,527,859 | 9,704,270 | 9,883,609 |
| Small Group | 146,860,999 | 149,186,953 | 153,710,763 | 155,691,294 | 142,353,239 | 130,574,548 |
| Large Group | 210,837,860 | 227,389,310 | 236,891,877 | 229,950,896 | 227,047,327 | 232,348,784 |
| Self-Funded | 38,276,829 | 36,839,566 | 36,359,574 | 36,169,727 | 36,034,058 | 35,346,998 |
| FEP | 93,363,351 | 98,601,288 | 104,094,720 | 109,299,456 | 114,764,429 | 120,502,650 |
| Medicaid | | | | | | |
| Stop Loss | 7,807,843 | 7,301,951 | 8,397,244 | 9,656,830 | 11,105,355 | 12,771,158 |
| Non-Risk Par | 13,159,674 | 12,917,804 | 12,948,421 | 12,948,421 | 12,948,421 | 12,948,421 |
| Total | 550,091,226 | 568,629,551 | 590,080,134 | 593,327,479 | 589,965,522 | 595,323,527 |

EXHIBIT
JOINT-50

**Blue Cross Blue Shield of Delaware**
**Stand Alone Basis - Five Year Forecast (2011 Through 2015) - Current Version**
**August 10, 2011**

| | | Forecast | | | | |
|---|---|---|---|---|---|---|
| | 2010 | 2011 | 2012 | 2013 | 2014 | 2015 |
| Incurred Care | | | | | | |
| Individual < 65 | 24,824,225 | 22,352,422 | 23,014,062 | 24,310,450 | 28,939,418 | 32,728,443 |
| Individual > 65 | 6,554,938 | 7,334,563 | 7,594,230 | 7,734,715 | 7,877,925 | 8,023,513 |
| Small Group | 117,578,327 | 118,754,901 | 122,355,916 | 123,932,447 | 113,315,169 | 103,939,165 |
| Large Group | 180,007,464 | 190,297,052 | 198,817,588 | 192,625,287 | 189,471,229 | 192,976,366 |
| Self-Funded | - | - | - | - | - | - |
| FEP | 89,282,889 | 94,667,954 | 99,942,246 | 104,939,358 | 110,186,326 | 115,695,642 |
| Medicaid | | | | | | |
| Stop Loss | 5,759,312 | 7,557,010 | 7,137,657 | 8,208,306 | 9,439,552 | 10,855,484 |
| Non-Risk Par | - | - | - | - | - | - |
| Total | 424,007,155 | 440,963,901 | 458,861,700 | 461,750,563 | 459,229,619 | 464,218,613 |
| Contribution Margin | | | | | | |
| Individual < 65 | 5,355,272 | 5,005,317 | 5,308,669 | 5,772,546 | 7,069,006 | 8,218,917 |
| Individual > 65 | 3,050,235 | 1,700,377 | 1,760,575 | 1,793,144 | 1,826,345 | 1,860,096 |
| Small Group | 29,282,672 | 30,432,053 | 31,354,847 | 31,758,847 | 29,038,071 | 26,635,382 |
| Large Group | 30,830,396 | 37,092,259 | 38,074,288 | 37,325,609 | 37,576,097 | 39,372,418 |
| Self-Funded | 38,276,829 | 36,839,566 | 36,359,574 | 36,169,727 | 36,034,058 | 35,346,998 |
| FEP | 4,080,462 | 3,933,334 | 4,152,474 | 4,360,098 | 4,578,103 | 4,807,008 |
| Medicaid | | | | | | |
| Stop Loss | 2,048,531 | (255,059) | 1,259,587 | 1,448,525 | 1,665,803 | 1,915,674 |
| Non-Risk Par | 13,159,674 | 12,917,804 | 12,948,421 | 12,948,421 | 12,948,421 | 12,948,421 |
| Total | 126,084,071 | 127,665,650 | 131,218,435 | 131,576,916 | 130,735,903 | 131,104,913 |
| Broker Fees | 17,497,338 | 17,773,946 | 18,288,169 | 17,764,800 | 16,707,192 | 15,962,650 |
| General & Administrative - Fixed | 92,868,452 | 47,940,000 | 49,378,200 | 50,859,546 | 52,385,332 | 53,956,892 |
| General & Administrative - Variable Ex. Medicaid | - | 50,812,909 | 51,327,899 | 49,968,642 | 48,551,891 | 47,054,041 |
| General & Administrative - Variable - Medicaid | - | - | - | - | - | - |
| General & Administrative - Affiliation | - | - | - | - | - | - |
| General & Administrative - Other | - | | - | - | - | - |
| General & Administrative - ITS AEA Reclass | 5,000,000 | | | | | |
| Corporate Initiatives - Health Care Reform | - | 400,000 | 400,000 | 400,000 | 400,000 | 400,000 |
| Corporate Initiatives - Affiliation / Integration | - | 2,500,000 | - | - | - | - |
| Corporate Initiatives - Medicaid Implementation | - | - | - | - | - | - |

**Blue Cross Blue Shield of Delaware**
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**August 10, 2011**

| | | Forecast | | | | |
|---|---|---|---|---|---|---|
| | **2010** | **2011** | **2012** | **2013** | **2014** | **2015** |
| Corporate Initiatives - Other | - | 500,000 | - | - | - | - |
| Disease Management - (Healthways Only) | - | 2,402,095 | 2,474,158 | 2,548,382 | 2,624,834 | 2,703,579 |
| 2011 Capital Expenditures - Depreciation | - | 700,000 | 2,326,667 | 2,326,667 | 1,630,000 | - |
| Capability Enhancements - Depreciation | - | - | - | 3,041,667 | 11,250,000 | 31,625,000 |
| Capability Enhancements - Support Expense | - | - | 324,000 | 1,966,500 | 6,399,000 | 9,751,500 |
| Integration Planning Consulting (See Note a) | - | - | - | - | - | - |
| Highmark Support Charges (See Note b) | | - | - | - | - | - |
| Affiliation Synergies (See Note c) | - | - | - | - | - | - |
| Affiliation Rebranding | - | - | - | - | - | - |
| Community Related Expense - Part 1 | 787,468 | 750,000 | 750,000 | 750,000 | 750,000 | 750,000 |
| Non Recurring Carveout, Net | | - | - | - | - | - |
| Total Operating Expenses | 116,153,258 | 123,778,950 | 125,269,092 | 129,626,204 | 140,698,248 | 162,203,662 |
| **Underwriting Gain/(Loss)** | **9,930,813** | **3,886,700** | **5,949,343** | **1,950,712** | **(9,962,345)** | **(31,098,749)** |
| Investment Income | 11,635,000 | 8,791,568 | 8,070,572 | 7,240,240 | 6,408,584 | 5,707,170 |
| FAS 115 | - | - | - | - | - | - |
| Income Before Taxes | 21,565,813 | 12,678,268 | 14,019,915 | 9,190,953 | (3,553,761) | (25,391,578) |
| Provision for Income Tax | 4,084,000 | 2,461,481 | 2,560,317 | 1,678,452 | (710,752) | (5,078,316) |
| Community Related Expense - Part 2 | 1,631,080 | 1,103,009 | 1,219,733 | 799,613 | - | - |
| Net Income/(Loss) from Operations | 15,850,733 | 9,113,778 | 10,239,866 | 6,712,888 | (2,843,009) | (20,313,263) |
| Non Recurring Carveout, Net | - | - | - | - | - | - |
| Net Income/(Loss) | 15,850,733 | 9,113,778 | 10,239,866 | 6,712,888 | (2,843,009) | (20,313,263) |
| SG&A expenses | 117,784,338 | 124,181,959 | 124,162,158 | 125,057,484 | 127,818,248 | 130,578,662 |
| Capability enhancements | - | 700,000 | 2,326,667 | 5,368,333 | 12,880,000 | 31,625,000 |
| Total operating expenses | 117,784,338 | 124,881,959 | 126,488,825 | 130,425,817 | 140,698,248 | 162,203,662 |
| Gain (loss) from operations | 8,299,733 | 2,783,691 | 4,729,610 | 1,151,099 | (9,962,345) | (31,098,749) |
| Investment income, net | 11,635,000 | 8,791,568 | 8,070,572 | 7,240,240 | 6,408,584 | 5,707,170 |
| Income (loss) before income taxes | 19,934,733 | 11,575,259 | 12,800,182 | 8,391,340 | (3,553,761) | (25,391,578) |

**Blue Cross Blue Shield of Delaware**
**Stand Alone Basis - Five Year Forecast (2011 Through 2015) - Current Version**
**August 10, 2011**

| | | | Forecast | | | |
|---|---|---|---|---|---|---|
| | **2010** | **2011** | **2012** | **2013** | **2014** | **2015** |
| Income taxes | 4,084,000 | 2,461,481 | 2,560,317 | 1,678,452 | (710,752) | (5,078,316) |
| Net income (loss) | 15,850,733 | 9,113,778 | 10,239,866 | 6,712,888 | (2,843,009) | (20,313,263) |
| | 116,153,258 | 124,232,629 | 125,697,632 | 131,555,367 | 144,083,276 | 166,992,365 |
| Impact of holding variable expense pmpm flat | - | (453,679) | (428,540) | (1,929,163) | (3,385,027) | (4,788,703) |
| **Revenue PMPM** | | | | | | |
| Individual < 65 | 270.85 | 275.07 | 301.20 | 329.81 | 361.14 | 395.45 |
| Individual > 65 | 227.44 | 220.35 | 231.37 | 242.94 | 255.09 | 267.84 |
| Small Group | 390.87 | 408.20 | 426.57 | 445.77 | 465.83 | 486.79 |
| Large Group | 359.00 | 381.76 | 399.71 | 420.49 | 443.20 | 467.57 |
| Self-Funded | 16.83 | 16.73 | 17.15 | 17.58 | 18.02 | 18.47 |
| FEP | 431.42 | 439.43 | 461.40 | 484.47 | 508.69 | 534.13 |
| Medicaid | - | | | | | |
| Stop Loss | NA | NA | NA | NA | NA | NA |
| Non-Risk Par | 11.23 | 10.55 | 10.55 | 10.55 | 10.55 | 10.55 |
| **Commercial Risk** | **355.95** | **374.89** | **393.83** | **414.25** | **434.39** | **456.88** |
| **Incurred Care PMPM** | | | | | | |
| Individual < 65 | 222.78 | 224.74 | 244.74 | 266.52 | 290.24 | 316.08 |
| Individual > 65 | 155.21 | 178.88 | 187.83 | 197.22 | 207.08 | 217.43 |
| Small Group | 312.93 | 324.94 | 339.56 | 354.84 | 370.81 | 387.49 |
| Large Group | 306.50 | 319.49 | 335.46 | 352.24 | 369.85 | 388.34 |
| Self-Funded | NA | NA | NA | NA | NA | NA |
| FEP | 412.56 | 421.90 | 442.99 | 465.14 | 488.40 | 512.82 |
| Medicaid | - | | | | | |
| Stop Loss | NA | NA | NA | NA | NA | NA |
| Non-Risk Par | NA | NA | NA | NA | NA | NA |
| **Loss Ratio (Excluding Quality Improvement)** | | | | | | |
| Individual < 65 | 82.3% | 81.7% | 81.3% | 80.8% | 80.4% | 79.9% |
| Individual > 65 | 68.2% | 81.2% | 81.2% | 81.2% | 81.2% | 81.2% |
| Small Group | 80.1% | 79.6% | 79.6% | 79.6% | 79.6% | 79.6% |
| Large Group | 85.4% | 83.7% | 83.9% | 83.8% | 83.5% | 83.1% |
| Self-Funded | NA | NA | NA | NA | NA | NA |
| FEP | 95.6% | 96.0% | 96.0% | 96.0% | 96.0% | 96.0% |

**Blue Cross Blue Shield of Delaware**
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**August 10, 2011**

| | | Forecast | | | | |
|---|---|---|---|---|---|---|
| | **2010** | **2011** | **2012** | **2013** | **2014** | **2015** |
| Medicaid | NA | | | | | |
| Stop Loss | 73.8% | 103.5% | 85.0% | 85.0% | 85.0% | 85.0% |
| Non-Risk Par | NA | NA | NA | NA | NA | NA |
| 833(b) MLR Calculation | 85.5% | 84.8% | 84.9% | 84.9% | 85.0% | 84.9% |
| **General & Administrative - pMpm** | | | | | | |
| General & Administrative - Fixed | | 10.09 | 10.39 | 10.70 | 11.02 | 11.36 |
| General & Administrative - Variable Ex. Medicaid | | 10.69 | 11.01 | 11.01 | 11.01 | 11.01 |
| General & Administrative - Variable - Medicaid | | 16.04 | 16.52 | 17.02 | 17.53 | 18.05 |
| General & Administrative - Other | | | | | | |
| **General & Administrative - Total** | **24.31** | **26.05** | **26.88** | **28.57** | **31.92** | **37.97** |
| Combined LG/FEP MLR | 88.5% | 87.4% | 87.6% | 87.7% | 87.7% | 87.5% |
| **Broker Commissions** | | | | | | |
| Individual < 65 | | | 6.20% | 5.78% | 5.19% | 4.84% |
| Individual > 65 | | | 1.40% | 1.36% | 1.32% | 1.28% |
| Small Group | | | 5.50% | 5.37% | 5.24% | 5.11% |
| Large Group | | | 2.90% | 2.81% | 2.72% | 2.63% |
| Self-Funded | | | 0.90% | 0.90% | 0.89% | 0.89% |
| Broker Commissions | | | | | | |
| Individual < 65 | | | 1,756,009 | 1,737,396 | 1,870,402 | 1,981,266 |
| Individual > 65 | | | 130,967 | 129,579 | 128,205 | 126,847 |
| Small Group | | | 8,454,092 | 8,358,158 | 7,459,293 | 6,678,396 |
| Large Group | | | 6,869,864 | 6,465,728 | 6,178,140 | 6,112,652 |
| Self-Funded | | | 327,236 | 323,940 | 321,150 | 313,490 |
| New Sales / Retention Programs | | | 750,000 | 750,000 | 750,000 | 750,000 |
| Total | | | 18,288,169 | 17,764,800 | 16,707,192 | 15,962,650 |
| Broker Commissions - Per Contract | | | | | | |
| Individual < 65 | | | 29.75 | 30.35 | 30.95 | 31.57 |
| Individual > 65 | | | 3.24 | 3.30 | 3.37 | 3.44 |
| Small Group | | | 44.51 | 45.40 | 46.31 | 47.24 |
| Large Group | | | 22.60 | 23.05 | 23.51 | 23.99 |
| Self-Funded | | | 0.30 | 0.30 | 0.31 | 0.31 |

**Blue Cross Blue Shield of Delaware**
**Stand Alone Basis - Five Year Forecast (2011 Through 2015) - Current Version**
**August 10, 2011**

| | | Forecast | | | | |
|---|---|---|---|---|---|---|
| | 2010 | 2011 | 2012 | 2013 | 2014 | 2015 |
| **Community Related Expense Detail** | | | | | | |
| State Tax Proxy | 836,583 | 750,000 | 750,000 | 750,000 | 750,000 | 750,000 |
| Community Contributions | 1,535,960 | 1,103,009 | 1,219,733 | - | - | - |
| Total | 2,372,543 | 1,853,009 | 1,969,733 | 750,000 | 750,000 | 750,000 |
| | | | | | | |
| Expected Net Income | | 9,113,778 | 10,239,866 | 6,712,888 | (2,843,009) | (20,313,263) |
| True Up Section | | 9,113,778 | 10,239,866 | 6,712,878 | (2,843,084) | (20,313,498) |
| Cash & Short Term Investments - % of Expenses | 6.5% | 6.0% | 6.0% | 6.0% | 6.0% | 6.0% |
| **Balance Sheet (GAAP Basis)** | | | | | | |
| | | - | - | - | - | - |
| Cash & Short Term Investments | 35,056,000 | 28,407,414 | 29,525,000 | 29,525,000 | 29,525,000 | 29,525,000 |
| Cash & Short Term Investments | | 5,500,000 | 5,500,000 | 5,800,000 | 6,200,000 | 7,800,000 |
| Investments | 239,664,000 | 244,352,292 | 216,823,267 | 196,904,752 | 169,300,048 | 156,823,974 |
| Uncollected Premiums | 12,169,000 | 16,518,758 | 17,131,207 | 17,010,122 | 16,604,530 | 16,550,172 |
| Amounts Receivable from Uninsured Plans | 11,485,000 | 12,059,250 | 12,662,213 | 13,295,323 | 13,960,089 | 14,658,094 |
| Property & Equipment, (Net) | 18,962,000 | 21,087,333 | 54,840,905 | 81,624,238 | 96,955,333 | 69,903,333 |
| Other | 31,346,000 | 33,346,000 | 35,346,000 | 37,346,000 | 39,346,000 | 41,346,000 |
| Total Assets | 348,682,000 | 361,271,047 | 371,828,591 | 381,505,435 | 371,891,001 | 336,606,573 |
| | | - | - | - | - | - |
| Short-term Borrowing | 9,930,000 | 9,930,000 | 9,930,000 | 9,930,000 | 9,930,000 | 9,930,000 |
| Unpaid Claims & Claim Adjustment Expense | 35,286,000 | 36,600,004 | 38,085,521 | 38,325,297 | 38,116,058 | 38,530,145 |
| Accounts Payable | 42,941,000 | 43,663,628 | 43,995,422 | 44,495,291 | 45,786,674 | 46,835,632 |
| Premiums Received in Advance | 10,737,000 | 10,324,224 | 10,707,004 | 10,631,326 | 10,377,831 | 10,343,858 |
| Other Liabilities | 63,334,000 | 63,334,000 | 63,334,000 | 63,334,000 | 63,334,000 | 63,334,000 |
| Other Liabilities | | 1,851,414 | 1,599,000 | 6,940,656 | 6,852,248 | 9,197,013 |
| Capital & Surplus | 186,454,000 | 195,567,778 | 205,807,644 | 212,520,532 | 209,677,523 | 189,364,260 |
| Total Liabilities, Capital & Surplus | 348,682,000 | 361,271,047 | 373,458,591 | 386,177,102 | 384,074,334 | 367,534,906 |
| Edit Check (Must Be Zero) | - | - | (1,630,000) | (4,671,667) | (12,183,333) | (30,928,333) |
| | | | | | | |
| **Balance Sheet (GAAP/SAP Adjustments & Non-Admitted Asset Impact)** | | | | | | |
| Cash & Short Term Investments | (1,329,000) | (9,930,000) | (9,930,000) | (9,930,000) | (9,930,000) | (9,930,000) |
| Investments | (8,421,000) | (8,500,000) | (8,500,000) | (8,500,000) | (8,500,000) | (8,500,000) |
| Uncollected Premiums | (818,000) | | | | | |

**Blue Cross Blue Shield of Delaware**
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**August 10, 2011**

| | | Forecast | | | | |
|---|---|---|---|---|---|---|
| | **2010** | **2011** | **2012** | **2013** | **2014** | **2015** |
| Amounts Receivable from Uninsured Plans | 234,000 | | | | | |
| Property & Equipment, (Net) | (14,177,000) | (15,726,481) | (50,352,790) | (77,690,582) | (93,812,335) | (67,229,577) |
| Other | (17,453,000) | (19,453,000) | (21,453,000) | (23,453,000) | (25,453,000) | (27,453,000) |
| Total Assets | (41,964,000) | (53,609,481) | (90,235,790) | (119,573,582) | (137,695,335) | (113,112,577) |
| | | | | | | |
| Short-term Borrowing | (9,930,000) | (9,930,000) | (9,930,000) | (9,930,000) | (9,930,000) | (9,930,000) |
| Unpaid Claims & Claim Adjustment Expense | 2,628,000 | | | | | |
| Accounts Payable | 1,990,000 | | | | | |
| Premiums Received in Advance | 3,057,000 | | | | | |
| Other Liabilities | (24,386,000) | (26,806,775) | (25,731,975) | (32,916,577) | (35,037,770) | (33,871,866) |
| Capital & Surplus | (15,323,000) | (16,872,706) | (56,203,815) | (81,398,672) | (104,910,898) | (100,239,044) |
| Total Liabilities, Capital & Surplus | (41,964,000) | (53,609,481) | (91,865,790) | (124,245,249) | (149,878,668) | (144,040,910) |
| Edit Check (Must Be Zero) | - | - | 1,630,000 | 4,671,667 | 12,183,333 | 30,928,333 |
| **Balance Sheet (SAP Basis)** | | | | | | |
| | - | | | | | |
| Cash & Short Term Investments | 33,727,000 | 23,977,414 | 25,095,000 | 25,395,000 | 25,795,000 | 27,395,000 |
| Investments | 231,243,000 | 235,852,292 | 208,323,267 | 188,404,752 | 160,800,048 | 148,323,974 |
| Uncollected Premiums | 11,351,000 | 16,518,758 | 17,131,207 | 17,010,122 | 16,604,530 | 16,550,172 |
| Amounts Receivable from Uninsured Plans | 11,719,000 | 12,059,250 | 12,662,213 | 13,295,323 | 13,960,089 | 14,658,094 |
| Property & Equipment, (Net) | 4,785,000 | 5,360,852 | 4,488,115 | 3,933,656 | 3,142,999 | 2,673,756 |
| Other | 13,893,000 | 13,893,000 | 13,893,000 | 13,893,000 | 13,893,000 | 13,893,000 |
| Total Assets | 306,718,000 | 307,661,566 | 281,592,801 | 261,931,853 | 234,195,666 | 223,493,996 |
| | | | | | | |
| Short-term Borrowing | - | - | - | - | - | - |
| Unpaid Claims & Claim Adjustment Expense | 37,914,000 | 36,600,004 | 38,085,521 | 38,325,297 | 38,116,058 | 38,530,145 |
| Accounts Payable | 44,931,000 | 43,663,628 | 43,995,422 | 44,495,291 | 45,786,674 | 46,835,632 |
| Premiums Received in Advance | 13,794,000 | 10,324,224 | 10,707,004 | 10,631,326 | 10,377,831 | 10,343,858 |
| Other Liabilities | 38,948,000 | 38,378,639 | 39,201,025 | 37,358,079 | 35,148,478 | 38,659,146 |
| Capital & Surplus | 171,131,000 | 178,695,072 | 149,603,829 | 131,121,860 | 104,766,625 | 89,125,216 |
| Total Liabilities, Capital & Surplus | 306,718,000 | 307,661,566 | 281,592,801 | 261,931,853 | 234,195,666 | 223,493,996 |
| | | 178,695,072 | 149,603,829 | 131,121,860 | 104,766,625 | 89,125,216 |
| Risk-Based Capital Ratio | 1,056 | 1,077 | 871 | 761 | 613 | 515 |
| Authorized Control Level (Dollars in Thousands) | 16,206,344 | 16,599,233 | 17,166,350 | 17,220,601 | 17,082,025 | 17,311,873 |
| Edit Check - Must Be Zero | - | - | - | - | - | - |

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**Stand Alone Basis - Five Year Forecast (2011 Through 2015) - Current Version**
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| | | Forecast | | | | |
|---|---|---|---|---|---|---|
| | 2010 | 2011 | 2012 | 2013 | 2014 | 2015 |
| **Statement of Cash Flows - Indirect Method (GAAP Basis)** | | | | | | |
| Operating Activities | | - | (0) | 10 | 75 | 235 |
| Net Income/(Loss) | 15,850,733 | 9,113,778 | 10,239,866 | 6,712,878 | (2,843,084) | (20,313,498) |
| Depreciation | | 8,874,667 | 9,491,667 | 12,533,333 | 20,207,000 | 38,952,000 |
| Decrease/(Increase) in Certain Assets | | (6,924,008) | (3,215,412) | (2,512,025) | (2,259,175) | (2,643,646) |
| Increase/(Decrease) in Liabilities | | 1,623,855 | 2,200,092 | 663,967 | 828,651 | 1,429,070 |
| Investing Activities | | | | | | |
| Purchase of Property & Equipment | | (8,000,000) | (41,245,238) | (37,316,667) | (33,538,095) | (9,900,000) |
| Other | | | (5,000,000) | | (10,000,000) | (20,000,000) |
| Financing Activities | | | | | | |
| Not Applicable | | - | - | - | - | - |
| Net Increase/(Decrease) in Cash | | 4,688,292 | (27,529,025) | (19,918,515) | (27,604,704) | (12,476,074) |
| Investments | | 244,352,292 | 216,823,267 | 196,904,752 | 169,300,048 | 156,823,974 |
| Investment Income Yield | | 4.0% | 4.0% | 4.0% | 4.0% | 4.0% |
| Investment Income | | 9,680,326 | 9,223,511 | 8,274,560 | 7,324,096 | 6,522,480 |
| Investment Management Fee | | 0.5% | 0.5% | 0.5% | 0.5% | 0.5% |
| Investment Management Expense | | 1,210,041 | 1,152,939 | 1,034,320 | 915,512 | 815,310 |
| Investment Income, Net | | 8,470,285 | 8,070,572 | 7,240,240 | 6,408,584 | 5,707,170 |
| | | 321,283 | | | | |
| **Statement of Cash Flows - Indirect Method (GAAP Basis) - Supporting Documentation** | | | | | | |
| Capital Expenditures | | | | | | |
| Routine | | 2,200,000 | 2,000,000 | 2,000,000 | 2,000,000 | 2,000,000 |
| Capability Enhancement | | 5,800,000 | 39,245,238 | 35,316,667 | 31,538,095 | 7,900,000 |
| Total | | 8,000,000 | 41,245,238 | 37,316,667 | 33,538,095 | 9,900,000 |
| Depreciation | | | | | | |
| Routine | | 3,000,000 | 2,000,000 | 2,000,000 | 2,000,000 | 2,000,000 |
| Capability Enhancement | | 696,667 | 2,326,667 | 5,368,333 | 12,880,000 | 31,625,000 |
| Total | | 3,696,667 | 4,326,667 | 7,368,333 | 14,880,000 | 33,625,000 |

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| | | Forecast | | | | |
|---|---|---|---|---|---|---|
| | 2010 | 2011 | 2012 | 2013 | 2014 | 2015 |
| Depreciation (Built into G&A Expense) | 3,814,000 | 3,800,000 | 3,800,000 | 3,800,000 | 3,962,000 | 3,962,000 |
| Enhanced Depreciation | | 1,378,000 | 1,365,000 | 1,365,000 | 1,365,000 | 1,365,000 |
| | 3,814,000 | 5,178,000 | 5,165,000 | 5,165,000 | 5,327,000 | 5,327,000 |
| **Property & Equipment GAAP / SAP** | | | | | | |
| **Property & Equipment - Routine** | | | | | | |
| Property & Equipment at 12/31/10 | 47,288,000 | 47,288,000 | 47,288,000 | 47,288,000 | 47,288,000 | 47,288,000 |
| Property & Equipment - Post 12/31/10 | | 2,200,000 | 4,200,000 | 6,200,000 | 8,200,000 | 10,200,000 |
| Accumulated Depreciation | (28,326,000) | (33,504,000) | (38,669,000) | (43,834,000) | (49,161,000) | (54,488,000) |
| Net | 18,962,000 | 15,984,000 | 12,819,000 | 9,654,000 | 6,327,000 | 3,000,000 |
| **Capability Enhancement** | | | | | | |
| Property & Equipment | | 5,800,000 | 45,045,238 | 80,361,905 | 111,900,000 | 119,800,000 |
| Accumulated Depreciation | | (696,667) | (3,023,333) | (8,391,667) | (21,271,667) | (52,896,667) |
| Net | - | 5,103,333 | 42,021,905 | 71,970,238 | 90,628,333 | 66,903,333 |
| **Property & Equipment - Total** | | | | | | |
| Property & Equipment | 47,288,000 | 53,088,000 | 92,333,238 | 127,649,905 | 159,188,000 | 167,088,000 |
| Accumulated Depreciation | (28,326,000) | (32,000,667) | (37,492,333) | (46,025,667) | (62,232,667) | (97,184,667) |
| Net | 18,962,000 | 21,087,333 | 54,840,905 | 81,624,238 | 96,955,333 | 69,903,333 |
| SAP Admitted Property & Equipmnet | | 5,360,852 | 4,488,115 | 3,933,656 | 3,142,999 | 2,673,756 |
| Non-Admitted Property & Equipment | (14,176,775) | (15,726,481) | (50,352,790) | (77,690,582) | (93,812,335) | (67,229,577) |
| Calculated Capital & Surplus | 171,131,000 | 178,695,072 | 149,603,829 | 131,121,860 | 104,766,625 | 89,125,216 |
| **True Up Section** | **171,131,000** | **178,695,072** | **149,603,829** | **131,121,860** | **104,766,625** | **89,125,216** |

# MEDICAL SOCIETY OF DELAWARE

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**Young Physicians Section**
NANCY FAN, M.D.

May 9, 2011

Linda Sizemore
Director of Company Regulation
Delaware Department of Insurance
841 Silver Lake Boulevard
Dover, Delaware 19904-2465

Dear Ms. Sizemore,

I wish to express my sincere gratitude and appreciation to you, to Insurance Commissioner Karen Weldin Stewart and Deputy Insurance Commissioner Gene Reed for facilitating the general information sessions and for allowing comments and letters regarding the proposed Highmark-Blue Cross Blue Shield of Delaware affiliation.

As President of the Medical Society of Delaware I am pleased and honored to submit this letter expressing the Society's support of the proposed affiliation between Highmark and Blue Cross Blue Shield of Delaware.

The Medical Society of Delaware believes the proposed affiliation between Blue Cross Blue Shield of Delaware and Highmark is a positive move and in the best interest of the citizens of our state for three main reasons:

1. Blue Cross Blue Shield of Delaware's viability depends upon alignment with a larger insurer;

2. The proposed transaction is an *affiliation* as opposed to an acquisition or merger; and

3. Highmark is the right partner for us here in Delaware.

Please allow me to elaborate on each of these three points:

First, Blue Cross Blue Shield of Delaware's viability depends upon an alignment with a larger insurer, allowing Blue Cross Blue Shield to remain competitive in the market place. Further, Blue Cross Blue Shield of Delaware must begin to position itself in the marketplace with technology platforms and infrastructure essential to survive in our uncertain climate of health care reform. The small business owners of Delaware, including physician practices, not to mention individual subscribers, cannot afford to lose another health care insurance plan. We have so few choices already.

EXHIBIT
JOINT-51

900 Prides Crossing • Newark, DE 19713-1600
PHONE: (302) 366-1400 or (800) 348-6800 • FAX: (302) 366-1354

Second, as indicated, the proposed transaction is an affiliation. It is not an acquisition or merger. This means Blue Cross Blue Shield of Delaware will maintain a strong local presence, with current senior management, a local board of directors, and assets all remaining here in Delaware. This is important to the Medical Society of Delaware, because we have worked hard over the years to establish and maintain a productive relationship based on trust and mutual respect with Blue Cross Blue Shield of Delaware. Although we do not always agree on issues, the important thing is that, in the true spirit of the *"Delaware Way,"* we find ways to collaborate so we can put patients first, provide quality care, and therefore, offer the best outcomes possible for all Delawareans. Health care is delivered locally. A patient's and an employer's insurance should be administered locally as well.

And, very importantly, this affiliation will allow jobs to remain in Delaware. One cannot stress this enough. This, as we all know, is absolutely critical to our state economy.

And the third reason − Highmark is the right partner for us in Delaware. Highmark is a stable organization and is financially strong. In today's economy, this is no small accomplishment. Its nonprofit status means that the patients' well-being and access to quality care should remain the priority, not Wall Street. Highmark's stability and financial position have allowed it to create an electronic infrastructure that is among the most sophisticated of any insurance company in the nation. This will be essential for everyone transitioning into the new era of health care reform.

If history is any guide, we can learn from other states where Highmark affiliations have occurred. In nearby West Virginia, the patients, physicians, and employers all seem quite satisfied with its presence in the market. Highmark has also made positive contributions to the state's economy by actually adding jobs, not reducing them. We believe this trend can occur here in Delaware, as Highmark surely will recognize the reasons why so many corporations call Delaware home.

In summary, the Medical Society of Delaware supports the affiliation between Blue Cross Blue Shield of Delaware and Highmark and it is my pleasure to respectfully submit such a letter of support. Again, thank you for the opportunity to provide comment. Your consideration of this important issue is greatly appreciated.

Sincerely,

David M. Bercaw, M.D.
President

Applicant Name (Company) Highmark Inc.

NAIC No. 54771-PA
FEIN: 23-1294723

**BIOGRAPHICAL AFFIDAVIT**

To the extent permitted by law, this affidavit will be kept confidential by the state insurance regulatory authority.

**(Print or Type)**

Full Name, Address and telephone number of the present or proposed entity under which this biographical statement is being required (Do Not Use Group Names). Highmark Inc.
120 Fifth Avenue
Pittsburgh, PA 15222
Phone: 412-544-7000

In connection with the above-named entity, I herewith make representations and supply information about myself as hereinafter set forth. (Attach addendum or separate sheet if space hereon is insufficient to answer any question fully.) IF ANSWER IS "NO" OR "NONE," SO STATE.

1. Affiant's Full Name (Initials Not Acceptable). Kenneth Rudolph Melani

2. a. Are you a citizen of the United States? Yes

   b. Are you a citizen of any other country, if so, what country? No

3. Affiant's Occupation or Profession. President and Chief Executive Officer

4. Affiant's business address. 120 Fifth Avenue, Pittsburgh, PA 15222

   Business telephone. [redacted]

5. Education and Training:

| College/ University | City/ State | Dates Attended (MM/YY) | Degree Obtained |
|---|---|---|---|
| Washington & Jefferson College | Washington, PA | 09/71 – 05/75 | B.A. |

| Graduate Studies: | College/ University | City/ State | Dates Attended (MM/YY) | Degree Obtained |
|---|---|---|---|---|
| Bowman Gray School of Medicine | Wake Forest Univ. | Winston-Salem, NC | 09/75 – 06/79 | M.D. |

| Other Training: Name | City/ State | Dates Attended (MM/YY) | Degree/Certification Obtained |
|---|---|---|---|
| None | | | |

(Note: If affiant attended a foreign school, please provide full address and telephone number of the college/university. If applicable, provide the foreign student Identification Number in the space provided in the Biographical Affidavit Supplemental Information.)

EXHIBIT
JOINT-52.1

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Applicant Name (Company) Highmark Inc.

NAIC No. 54771-PA
FEIN: 23-1294723

6. List of memberships in professional societies and associations.

| Name of Society/Association | Contact Name | Address of Society/Association | Telephone Number of Society/Association |
|---|---|---|---|
| Please see Attachment | | | |

7. Present or proposed position with the applicant entity. Officer and Director

8. List complete employment record for the past twenty (20) years, whether compensated or otherwise (up to and including present jobs, positions, partnerships, owner of an entity, administrator, manager, operator, directorates or officerships). Please list the most recent first. Attach additional pages if the space provided is insufficient. It is only necessary to provide telephone numbers and supervisory information for the past ten (10) years.

Beginning/Ending Dates (MM/YY) 01/1/03 - Present Employer's Name Highmark Inc.

Address 120 Fifth Avenue City Pittsburgh State/Province PA

Country USA Postal Code 15222 Phone [redacted] Offices/Positions Held President and CEO

Supervisor / Contact [redacted]

Beginning/Ending Dates (MM/YY) 12/96 - 12/31/02 Employer's Name Highmark Inc.

Address 120 Fifth Avenue City Pittsburgh State/Province PA

Country USA Postal Code 15222 Phone 412-544-7245 Offices/Positions Held Exec. VP, Strategic Business Dev.

Supervisor/Contact John S. Brouse (Contact Human Resources)

Beginning/Ending Dates (MM/YY) 1989 - 12/96 Employer's Name Blue Cross of Western Pennsylvania

Address 120 Fifth Avenue City Pittsburgh State/Province PA

Country USA Postal Code 15222 Phone 412-544-7245 Offices/Positions Held Executive Vice President

Supervisor/Contact Jim Klingensmith (Contact Human Resources)

Beginning/Ending Dates (MM/YY) 1988 - 1989 Employer's Name West Penn Cares

Address City Pittsburgh State/Province PA

Country USA Postal Code Phone Offices/Positions Held President & CEO

Supervisor/Contact

Please see attachment for additional information

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Applicant Name (Company) Highmark Inc. NAIC No. 54771-PA
FEIN: 23-1294723

9. a. Have you ever been in a position which required a fidelity bond? Yes. All employees, directors and officers of Highmark Inc. and its subsidiary corporations are covered under a fidelity policy, subject to certain policy terms, limits, conditions and exclusions. If any claims were made on the bond, give details. None

b. Have you ever been denied an individual or position schedule fidelity bond, or had a bond canceled or revoked? If yes, give details. No

10. List any professional, occupational and vocational licenses (including licenses to sell securities) issued by any public or governmental licensing agency or regulatory authority or licensing authority that you presently hold or have held in the past. For any non-insurance regulatory issuer, identify and provide the name, address and telephone number of the licensing authority or regulatory body having jurisdiction over the license (s) issued.. If your professional license number is your Social Security Number (SSN) or embeds your SSN or any sequence of more than five numbers that are reasonably identifiable as your SSN, then write SSN for that portion of the professional license number that is represented by your SSN. (For example, "SSN", "12-SSN-345" or "1234-SSN" (last 6 digits)). Attach additional pages if the space provided is insufficient

Organization/Issuer of License PA Dept. of State Bureau of Prof. & Occup. Affairs Address P.O. Box 2649

City Harrisburg State/Province PA Country USA Postal Code 17105

License Type Medical Phy. & Surgeon License # MD023844-E Date Issued (MM/YY) 7/11/80

Date Expired (MM/YY) Not Expired Reason for Termination Not applicable

Non-insurance Regulatory Phone Number (if known 717-787-8503

Organization /Issuer of License Drug Enforcement Administration Address P.O. Box 28083

City Washington State/Province DC Country USA Postal Code 20038-8083

License Type DEA License # BM2892241 Date Issued (MM/YY) Not Available

Date Expired (MM/YY) Not Expired Reason for Termination Not applicable

Non-insurance Regulatory Phone Number (if known) 800-882-9539

11. In responding to the following, if the record has been sealed or expunged, and the affiant has personally verified that the record was sealed or expunged, an affiant may respond "no" to the question. Have you ever:

a. Been refused an occupational, professional, or vocational license or permit by any regulatory authority, or any public administrative, or governmental licensing agency?
No

b. Had any occupational, professional, or vocational license or permit you hold or have held, been subject to any judicial, administrative, regulatory, or disciplinary action?
No

c. Been placed on probation or had a fine levied against you or your occupational, professional, or vocational license or permit in any judicial, administrative, regulatory, or disciplinary action? No

d. Been charged with, or indicted for, any criminal offense(s) other than civil traffic offenses? No

e. Pled guilty, or nolo contendere, or been convicted of, any criminal offense(s) other than civil traffic offenses?
No

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f. Had adjudication of guilt withheld, had a sentence imposed or suspended, had pronouncement of a sentence suspended, or been pardoned, fined, or placed on probation, for any criminal offense(s) other than civil traffic offenses? No

g. Been subject to a cease and desist letter or order, or enjoined, either temporarily or permanently, in any judicial, administrative, regulatory, or disciplinary action, from violating any federal, state law or law of another country regulating the business of insurance, securities or banking, or from carrying out any particular practice or practices in the course of the business of insurance, securities or banking? No

h. Been, within the last ten (10) years, a party to any civil action involving dishonesty, breach of trust, or a financial dispute? No

i. Had a finding made by the Comptroller of any state or the Federal Government that you have violated any provisions of small loan laws, banking or trust company laws, or credit union laws, or that you have violated any rule or regulation lawfully made by the Comptroller of any state or the Federal Government? No

j. Had a lien or foreclosure action filed against you or any entity while you were associated with that entity? No

If the response to any question above is answered "Yes", please provide details including dates, locations, disposition, etc. Attach a copy of the complaint and filed adjudication or settlement as appropriate.

12. List any entity subject to regulation by an insurance regulatory authority that you control directly or indirectly. The term "control" (including the terms "controlling," "controlled by" and "under common control with") means the possession, direct or indirect, of the power to direct or cause the direction of the management and policies of a person, whether through the ownership of voting securities, by contract other than a commercial contract for goods or non-management services, or otherwise, unless the power is the result of an official position with or corporate office held by the person. Control shall be presumed to exist if any person, directly or indirectly, owns, controls, holds with the power to vote, or holds proxies representing, ten percent (10%) or more of the voting securities of any other person. None

If any of the stock is pledged or hypothecated in any way, give details.

13. Do [Will] you or members of your immediate family individually or cumulatively subscribe to or own, beneficially or of record, 10% or more of the outstanding shares of stock of any entity subject to regulation by an insurance regulatory authority, or its affiliates? An "affiliate" of, or person "affiliated" with, a specific person, is a person that directly, or indirectly through one or more intermediaries, controls, or is controlled by, or is under common control with, the person specified. If the answer is "Yes", please identify the company or companies in which the cumulative stock holdings represent 10% or more of the outstanding voting securities.
No

If any of the shares of stock are pledged or hypothecated in any way, give details.

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Applicant Name (Company) Highmark Inc. NAIC No. 54771-PA
FEIN: 23-1294723

14. Have you ever been adjudged a bankrupt? No If yes, provide details

15. To your knowledge has any company or entity for which you were an officer or director, trustee, investment committee member, key management employee or controlling stockholder, had any of the following events occur while you served in such capacity? If yes, please indicate and give details. When responding to questions (b) and (c) affiant should also include any events within twelve (12) months after his or her departure from the entity.

a. Been refused a permit, license, or certificate of authority by any regulatory authority, or Governmental-licensing agency? No

b. Had its permit, license, or certificate of authority suspended, revoked, canceled, non-renewed, or subjected to any judicial, administrative, regulatory, or disciplinary action (including rehabilitation, liquidation, receivership, conservatorship, federal bankruptcy proceeding, state insolvency, supervision or any other similar proceeding)? No

c. Been placed on probation or had a fine levied against it or against its permit, license, or certificate of authority in any civil, criminal, administrative, regulatory, or disciplinary action? Yes. Please see attachment

Note: If an affiant has any doubt about the accuracy of an answer, the question should be answered in the positive and an explanation provided.

Dated and signed this 31st day of October 2010 at Camp Hill Pa I hereby certify under penalty of perjury that I am acting on my own behalf, and that the foregoing statements are true and correct to the best of my knowledge and belief.

(Signature of Affiant)

State of Pennsylvania County of Cumberland

The foregoing instrument was acknowledged before me this 31st day of October, 2010 By Kenneth Rudolph Melani, and:

☒ who is personally known to me, or

☐ who produced the following identification:

[SEAL]

NOTARIAL SEAL
ROBIN L MCKOY
Notary Public
SUSQUEHANNA TWP, DAUPHIN COUNTY
My Commission Expires Nov 29, 2013

Notary Public

Robin L McKoy
Printed Notary Name

11/29/2013
My Commission Expires

Applicant Name (Company) Highmark Inc.

NAIC No. 54771-PA
FEIN: 23-1294723

**BIOGRAPHICAL AFFIDAVIT**
**Supplemental Personal Information**

**(Print or Type)**

To the extent permitted by law, this affidavit will be kept confidential by the state insurance regulatory authority.

Full Name, Address, and telephone number of the present or proposed entity under which this biographical statement is being required (Do Not Use Group Names).

Highmark Inc.

120 Fifth Avenue

Pittsburgh, PA 15222

1. Affiant's Full Name (Initials Not Acceptable). Kenneth Rudolph Melani

2. Have you ever used any other name including nickname, maiden name or aliases? No If yes, give the reason if any, if none indicate such, and provide the full name(s) and date(s) used.

| Beginning/Ending Date(s) Used (MM/YY) | Name(s) | Reason (If None, indicate such) |
|---|---|---|
| - | | |
| - | | |
| - | | |
| - | | |
| - | | |
| - | | |
| - | | |
| - | | |
| - | | |

Note: Dates provided in response to this question may be approximate. Parties using this form understand that there could be an overlap of dates when transitioning from one name to another.

3. Affiant's Social Security Number [redacted]

4. Government Identification Number if not a U.S. Citizen None

5. Foreign Student ID# (if applicable) None

6. Date of Birth: (MM/DD/YY) 10/08/53 Place of Birth: City New Kensington
State/Province PA Country USA

7 Name of Affiant's Spouse (if applicable) [redacted]

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Applicant Name (Company) Highmark Inc. NAIC No. 54771-PA
FEIN: 23-1294723

8. List your residences for the last ten (10) years starting with your current address, giving:

| Beginning/Ending Dates (MM/YY) | Address | City | State/ Province | Country | Postal Code |
|---|---|---|---|---|---|
| 1985 – Present | [redacted] | | PA | USA | [redacted] |
| | | | | | |
| | | | | | |
| | | | | | |

Note: Dates provided in response to this question may be approximate, except for current address. Parties using this form understand that there could be an overlap of dates when transitioning from one address to another.

Dated and signed this 31st day of October, 2010 at Camp Hill PA I hereby certify under penalty of perjury that I am acting on my own behalf, and that the foregoing statements are true and correct to the best of my knowledge and belief.

Kenneth R. Melani
(Signature of Affiant)

State of Pennsylvania County of Cumberland

The foregoing instrument was acknowledged before me this 31st day of October, 2010 By Kenneth Rudolph Melani, and:

☒ who is personally known to me, or

☐ who produced the following identification: _____

[SEAL]

NOTARIAL SEAL
ROBIN L MCKOY
Notary Public
SUSQUEHANNA TWP, DAUPHIN COUNTY
My Commission Expires Nov 29, 2013

Robin L McKoy
Notary Public

Robin L McKoy
Printed Notary Name

11/29/2013
My Commission Expires

Applicant Name (Company) Highmark Inc.

NAIC No. 54771-PA
FEIN: 23-1294723

**DISCLOSURE AND AUTHORIZATION CONCERNING BACKGROUND REPORTS (*All states except California, Minnesota and Oklahoma)***

This Disclosure and Authorization is provided to you in connection with pending or future application(s) of Highmark Inc. ("Company") for licensure or a permit to organize ("Application") with a department of insurance in one or more states within the United States. Company desires to procure a consumer or investigative consumer report (or both)("Background Reports") regarding your background for review by a department of insurance in any state where Company pursues an Application during the term of your functioning as, or seeking to function as, an officer, member of the board of directors or other management representative ("Affiant") of Company or of any business entities affiliated with Company ("Term of Affiliation") for which a Background Report is required by a department of insurance reviewing any Application. Background Reports requested pursuant to your authorization below may contain information bearing on your character, general reputation, personal characteristics, mode of living and credit standing. The purpose of such Background Reports will be to evaluate the Application and your background as it pertains thereto. To the extent required by law, the Background Reports procured under this Disclosure and Authorization will be maintained as confidential.

You may obtain copies of any Background Reports about you from the consumer reporting agency ("CRA") that produces them. You may also request more information about the nature and scope of such reports by submitting a written request to Company. To obtain contact information regarding CRA or to submit a written request for more information, contact Carrie J. Pecht, Esq., Highmark Inc., 1800 Center Street, Camp Hill, PA 17089 Phone: 717-302-4226

Attached for your information is a "Summary of Your Rights Under the Fair Credit Reporting Act."

**AUTHORIZATION:** I am currently an Affiant of Company as defined above. I have read and understand the above Disclosure and by my signature below, I consent to the release of Background Reports to a department of insurance in any state where Company files or intends to file an Application, and to the Company, for purposes of investigating and reviewing such Application and my status as an Affiant. I authorize all third parties who are asked to provide information concerning me to cooperate fully by providing the requested information to CRA retained by Company for purposes of the foregoing Background Reports, except records that have been erased or expunged in accordance with law.

I understand that I may revoke this Authorization at any time by delivering a written revocation to Company and that Company will, in that event, forward such revocation promptly to any CRA that either prepared or is preparing Background Reports under this Disclosure and Authorization. This Authorization shall remain in full force and effect until the earlier of (i) the expiration of the Term of Affiliation, (ii) written revocation as described above, or (iii) twelve (12) months following the date of my signature below.

A true copy of this Disclosure and Authorization shall be valid and have the same force and effect as the signed original.

Kenneth Rudolph Melani, [redacted]
(Printed Full Name and Residence Address)

(Signature) 10/21/10 (Date)

State of Pennsylvania County of Cumberland

The foregoing instrument was acknowledged before me this 21st day of Oct 2010 By

Kenneth Rudolph Melani, and

☒ who is personally known to me, or

☐ who produced the following identification: _____

[SEAL]

NOTARIAL SEAL
ROBIN L MCKOY
Notary Public
SUSQUEHANNA TWP, DAUPHIN COUNTY
My Commission Expires Nov 29, 2013

Notary Public

Robin L. McKoy
Printed Notary Name

11/29/2013
My Commission Expires

Applicant Name (Company) Highmark Inc.

NAIC No. 54771-PA
FEIN: 23-1294723

**Kenneth R. Melani, M.D.**
**Attachment**

6. List of memberships in professional societies and associations.

| Name of Society/Association | Contact Name | Address of Society/Association | Telephone Number of Society/Assoc. |
|---|---|---|---|
| American Medical Association | | 515 N. State St., Chicago, IL 06010 | 800-621-8335 |
| Pennsylvania Medical Society | | 777 East Park Dr., Harrisburg, PA 17105 | 717-558-7750 |
| Allegheny County Medical Society | | 713 Ridge Ave., Pittsburgh, PA 15212 | 412-321-5030 |
| American Society of Internal Medicine American College of Physicians | | 190 N. Independence Mall West, Phila., PA 19106 | 800-338-2746 |
| American College of Physician Executives | | 4890 West Kennedy Blvd., Tampa, FL 33609 | 800-562-8088 |

8. List complete employment record for the past twenty (20) years, whether compensated or otherwise (up to and including present jobs, positions, partnerships, owner of an entity, administrator, manager, operator, directorates, or officerships). Please list the most recent first. Attach additional pages if the space provided is insufficient. It is only necessary to provide telephone numbers and supervisory information for the past ten (10) years.

Beginning/Ending Dates (MM/YY) 1982 - 1988 Employer's Name Melani & Wilfong, P.C.

Address Mellon Pavilion, Liberty Ave. City Pittsburgh State/Province PA

Country USA Postal Code 15222 Phone Not Available Offices/Positions Held Practicing Physician

Supervisor/Contact Not Available

In addition to the preceding information, I currently serve or have served as referenced below.

| Corporation/Association | Position Held | Dates |
|---|---|---|
| Caring Foundation<br>120 Fifth Avenue<br>Pittsburgh, PA 15222-3099 | Director | 2/28/03 – 6/07 |
| Gateway Health Plan, L.P.<br>Two Chatham Center, Ste. 500<br>Pittsburgh, PA 15219 | Director/Secretary | 1/97 - 12/10/02 |
| Keystone Health Plan West, Inc.<br>120 Fifth Avenue<br>Pittsburgh, PA 15222 | President & CEO | 5/98 - 2/28/03 |
| Highmark West Virginia Inc.<br>700 Market Square<br>P.O. Box 1948<br>Parkersburg, WV 26101 | Director<br>Chairperson | 5/98 – 5/07<br>5/12/05 – 5/07 |
| Davis Vision, Inc.<br>159 Express Street<br>Plainview, NY 11803 | Director | 02/17/05-6/11/07 |

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Applicant Name (Company) Highmark Inc.

NAIC No. 54771-PA
FEIN: 23-1294723

| Corporation/Association | Position Held | Dates |
|---|---|---|
| HVHC Inc.<br>1013 Centre Road<br>Wilmington, DE 19805 | Director<br>Chairman | 02/17/05-6/11/07<br>09/11/06-6/11/07 |
| DVSC, Inc.<br>1800 Center Street<br>Camp Hill, PA 17089 | Director | 02/17/05-5/16/06 |
| Davis Vision IPA, Inc.<br>159 Express Street<br>Plainview, NY 11803 | Director | 02/17/05-5/16/06 |
| Davis Vision of Nevada, Inc.<br>333 South Maryland Parkway<br>Las Vegas, NV 89109 | Director | 02/17/05-5/16/06 |
| Empire Vision Center, Inc.<br>2921 Erie Boulevard East<br>Syracuse, NY 13224 | Director | 02/17/05-5/16/06 |
| Viva Optique, Inc.<br>3140 Route 22 West<br>Somerville, NJ 08676 | Director | 02/17/05-6/11/07 |
| ECCA Holdings Corporation<br>2711 Centerville Rd., Ste. 400<br>Wilmington, DE 19808 | Director | 8/1/06 – 6/11/07 |
| Eye Care Centers of America, Inc.<br>11103 West Avenue<br>San Antonio, TX 78213 | Director | 8/1/06 – 6/11/07 |
| United Concordia Companies, Inc.<br>4401 Deer Path Road<br>Harrisburg, PA 17110 | Chairman<br>Director | 9/26/06 – 5/24/07<br>02/21/05-5/23/07 |
| Parker Benefits, Inc.<br>700 Market Square<br>P.O. Box 1948<br>Parkersburg, WV 26101 | Director | 5/12/05 – 5/07 |
| HM Life Insurance Company of New York<br>420 Fifth Avenue, 3rd Floor<br>New York, NY 10018 | Director<br>Chairman | 04/19/05-5/25/07<br>6/26/06 – 5/25/07 |
| Highmark Casualty Insurance Company<br>120 Fifth Avenue<br>Pittsburgh, PA 15222 | Director<br>Chairman | 04/19/05-5/25/07<br>9/26/06 – 5/25/07 |
| HM Life Insurance Company<br>120 Fifth Avenue<br>Pittsburgh, PA 15222 | Director<br>Chairman | 04/19/05-5/25/07<br>6/26/06 – 5/25/07 |

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Applicant Name (Company) Highmark Inc.

NAIC No. 54771-PA
FEIN: 23-1294723

| Corporation/Association | Position Held | Dates |
|---|---|---|
| HM Insurance Group<br>120 Fifth Avenue<br>Pittsburgh, PA 15222 | Director<br>Chairman | 4/19/05 – 5/25/07<br>9/26/06 – 5/25/07 |
| HM Broker Services, Inc.<br>120 Fifth Avenue<br>Pittsburgh, PA 15222 | Director<br>Chairman | 4/19/05 – 5/25/07<br>9/26/06 – 5/25/07 |
| HM Benefits Administrators, Inc.<br>120 Fifth Avenue<br>Pittsburgh, PA 15222 | Director<br>Chairman | 4/19/05 – 5/25/07<br>9/26/06 – 5/25/07 |
| Highmark Senior Resources, Inc.<br>120 Fifth Avenue<br>Pittsburgh, PA 15222 | Director | 02/08/05-06/02/06 |
| HM Health Insurance Company<br>120 Fifth Avenue<br>Pittsburgh, PA 15222 | Director<br>Director<br>President<br>President & CEO | 08/01/05 – 9/18/06<br>06/30/10 - Present<br>08/01/05 – 9/18/06<br>06/30/10 - Present |
| HMO Northeastern Pennsylvania, Inc.<br>d/b/a First Priority Health<br>19 North Main Street<br>Wilkes-Barre, PA 18711 | Director | 4/29/05 – 5/31/06 |
| First Priority Life Insurance Company, Inc.<br>d/b/a First Priority Life<br>19 North Main Street<br>Wilkes-Barre, PA 18711 | Director | 4/29/05 – 5/31/06 |
| Highmark Medicare Services, Inc.<br>1800 Center Street<br>Camp Hill, PA 17089 | Director | 9/21/06 – 11/10/06 |
| Highmark Ventures Inc.<br>120 Fifth Avenue<br>Pittsburgh, PA 15222 | Director | 8/16/10 – Present |
| National Institute for Health Care Management, Inc.<br>1225 19th St., NW, Ste. 710<br>Washington, DC 20036-2454 | Director | Present |

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**Kenneth R. Melani, M.D.**
**Attachment**

15. To your knowledge, has any company or entity for which you were an officer or director, trustee, investment committee member, key management employee, or controlling stockholder, had any of the following events occur while you served in such capacity? If yes, please indicate and give details. When responding to questions (b) and (c), affiant should also include any events within twelve (12) months after his or her departure from the entity.

c. Been placed on probation or had a fine levied against it or against its permit, license, or certificate of authority in any civil, criminal, administrative, regulatory, or disciplinary action? Yes – please see below

**Highmark Inc.**

On November 15, 2005, Highmark entered into a Conciliation Agreement with the Federal Election Commission ("FEC"). The Conciliation Agreement was entered to resolve an issue relating to improper corporate contributions in violation of the Federal Election Campaign Act. The violations stemmed from the unauthorized activities of a former employee who caused approximately $54,000 of Highmark corporate funds to be used to defray expenses of fundraising events sponsored by the campaign finance or political action committees of an elected federal official. This conduct was self-disclosed by Highmark to the FEC in March 2004. As part of the Conciliation Agreement, Highmark agreed to pay a civil penalty of $54,078 to the FEC.

Highmark Inc. entered into a Consent Order with the Pennsylvania Insurance Department dated December 23, 2002 regarding allegations of issuance of provider contract forms that had not yet been approved by that Department. A civil penalty of $300,000 was paid at the time in settlement of the allegations. The Consent Order included a cease and desist prohibiting use of unapproved provider contract forms.

Highmark Inc. entered into a Consent Order with the Pennsylvania Insurance Department dated December 26, 2003 as a result of an inadvertent coding error in Highmark Inc.'s claims processing system. Six claims for childhood immunizations were initially denied and, after further review, were later paid. A civil penalty of $3,000 was paid at the time in settlement of the allegations and the coding error was corrected. The Consent Order included a cease and desist provision prohibiting activities of this type subject to the Consent Order.

Blue Cross of Western Pennsylvania (a predecessor corporation to Highmark Inc.) entered into a Consent Order with the Pennsylvania Insurance Department in March of 1993 regarding allegations of violations of the Pennsylvania Hospital Plan Corporation Law and the Pennsylvania Unfair Insurance Practices Act. The violative practices included failure to obtain prior approval of contract forms and corresponding rates and notifying agents that certain sales of medical coverage must include the sale of life and accidental death and dismemberment coverage. The order contained a cease and desist from the violative activities and the assessment of a $5,000 penalty.

**Keystone Health Plan West, Inc.**

Market Conduct Examination that covered the period July 1, 1998 to June 30, 1999 - Payment of $200,000 made to the Commonwealth of Pennsylvania in settlement of all violations contained in the report.

Market Conduct Examination that covered the period May 1, 2001 to July 31, 2001. Focused on the Company's operation in areas addressed by the recommendations made as a result of the last examination, requirements of Act 68 of 1998 and coverage of mandated benefits. Payment of $30,000 made to the Commonwealth of Pennsylvania in settlement of all violations contained in the report.

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**Davis Vision, Inc. License Revocations:**
Certain certificates of authority held by Davis Vision, Inc. were revoked by the states of Maryland, Arkansas and Oklahoma due primarily to administrative errors related to tax, annual report or other required filings. The revocations had no material adverse effect on the business and all certificates of authority were subsequently reinstated.

**Davis Vision, Inc.:**

New York: In September 2007, Davis Vision, Inc. was notified by the State of New York Insurance Department that it had not identified the assessment of a fine by the Nevada Division of Insurance in 2002 in a renewal application for a life/accident and health license under section 2103(a) of New York insurance law. The Company entered into a Stipulation which included a fine in the amount of $500. The Company implemented corrective action measures to avoid future inadvertent omissions.

Maine: In September 2006, Davis Vision, Inc. was notified by the State of Maine Bureau of Insurance that it had not disclosed the administrative proceeding to which it was a party with the State of Nevada upon submission of an application to the State of Maine for a Non-Resident Producer Business Entity license. In August 2007, Davis Vision entered into a Consent Agreement and remitted an administrative penalty in the amount of $250, following which the Producer license was issued.

Nevada: In March 2006, Davis Vision, Inc. was notified by the State of Nevada Department of Business and Industry that the Company's annual report required in connection with its third party administrator activities in that state was not timely filed and was incomplete, in violation of Nevada laws governing third party administrators. The Company consented, via a Consent to Fine, to an administrative penalty in the amount of $500.

**Empire Vision Center, Inc.**

Massachusetts: Docket No. OP-07-2002
In November 2006, Empire Vision Center, Inc. (Empire) entered into a Consent Agreement with the Commonwealth of Massachusetts, Board of Registration of Optometrists (the Board) arising out of the Board's complaint alleging that Empire had violated Massachusetts General Laws governing the unlicensed practice of optometry, by controlling or directing the actions or decisions of optometrists. Empire agreed to enumerated conditions in the Consent Agreement and paid a fine in the amount of $10,000.

**HM Health Insurance Company**

Trigon Health and Life Insurance Company (now HM Health Insurance Company) failed to submit a 2003 Annual Certification of Advertisement Report as required by a provision of Nevada Insurance Code that requires insurers to file an Annual Certification of Advertisement Report on or before December 31st of each year. The failure to submit the Report occurred under prior ownership. The Corporation submitted to the Nevada Division of Insurance an executed Consent to Fine, a penalty of $500 and the 2003 Annual Certification of Advertisement Report.

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Applicant Name (Company) Highmark Inc.

NAIC No. 54771
FEIN: 23-1294723

**BIOGRAPHICAL AFFIDAVIT**

To the extent permitted by law, this affidavit will be kept confidential by the state insurance regulatory authority.

**(Print or Type)**

Full Name, Address and telephone number of the present or proposed entity under which this biographical statement is being required (Do Not Use Group Names). Highmark Inc.

120 Fifth Avenue

Pittsburgh, PA 15222

412-544-7000

In connection with the above-named entity, I herewith make representations and supply information about myself as hereinafter set forth. (Attach addendum or separate sheet if space hereon is insufficient to answer any question fully.) IF ANSWER IS "NO" OR "NONE," SO STATE.

1. Affiant's Full Name (Initials Not Acceptable). Deborah Lynn Rice
2. a. Are you a citizen of the United States? Yes

   b. Are you a citizen of any other country, if so, what country? No
3. Affiant's Occupation or Profession. Executive Vice President, Health Services
4. Affiant's business address. 120 Fifth Avenue, Ste. 3128, Pittsburgh, PA 15222

   Business telephone. [redacted]
5. Education and Training:

| College/ University | City/ State | Dates Attended (MM/YY) | Degree Obtained |
|---|---|---|---|
| Carlow College | Pittsburgh, PA | | Business |

| Graduate Studies: | College/ University | City/ State | Dates Attended (MM/YY) | Degree Obtained |
|---|---|---|---|---|
| | | | | |

| Other Training: Name | City/ State | Dates Attended (MM/YY) | Degree/Certification Obtained |
|---|---|---|---|
| | | | |

(Note: If affiant attended a foreign school, please provide full address and telephone number of the college/university. If applicable, provide the foreign student Identification Number in the space provided in the Biographical Affidavit Supplemental Information.)

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EXHIBIT
JOINT-53.1

Applicant Name (Company) Highmark Inc.

NAIC No. 54771
FEIN: 23-1294723

6. List of memberships in professional societies and associations.

| Name of Society/Association | Contact Name | Address of Society/Association | Telephone Number of Society/Association |
|---|---|---|---|
| None | | | |

7. Present or proposed position with the applicant entity. Officer – EVP, Health Services

8. List complete employment record for the past twenty (20) years, whether compensated or otherwise (up to and including present jobs, positions, partnerships, owner of an entity, administrator, manager, operator, directorates or officerships). Please list the most recent first. Attach additional pages if the space provided is insufficient. It is only necessary to provide telephone numbers and supervisory information for the past ten (10) years.

Beginning/Ending
Dates (MM/YY) 04/82 - Present Employer's Name Highmark Inc.

Address/City 120 Fifth Avenue, Pittsburgh State/Province PA

Country USA Postal Code 15222-3099 Phone 412-544-4700 Offices/Positions Held
Executive Vice President (5/27/09 – Present) Senior Vice President

Supervisor / Contact [redacted]

Beginning/Ending
Dates (MM/YY)_____ - _____ Employer's Name _____

Address City _____ State/Province _____

Country _____ Postal Code _____ Phone _____ Offices/Positions Held _____

Supervisor / Contact _____

Beginning/Ending
Dates (MM/YY)_____ - _____ Employer's Name _____

Address City _____ State/Province _____

Country _____ Postal Code _____ Phone _____ Offices/Positions Held _____

Supervisor / Contact _____

Beginning/Ending
Dates (MM/YY)_____ - _____ Employer's Name _____

Address City _____ State/Province _____

Country _____ Postal Code _____ Phone _____ Offices/Positions Held _____

Supervisor / Contact _____

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9. a. Have you ever been in a position which required a fidelity bond? Yes If any claims were made on the bond, give details.
All employees, directors and officers of Highmark and its subsidiary corporations are covered under a fidelity policy, subject to certain policy terms, conditions and exclusions.

b. Have you ever been denied an individual or position schedule fidelity bond, or had a bond canceled or revoked? If yes, give details. No

10. List any professional, occupational and vocational licenses (including licenses to sell securities) issued by any public or governmental licensing agency or regulatory authority or licensing authority that you presently hold or have held in the past. For any non-insurance regulatory issuer, identify and provide the name, address and telephone number of the licensing authority or regulatory body having jurisdiction over the license (s) issued.. If your professional license number is your Social Security Number (SSN) or embeds your SSN or any sequence of more than five numbers that are reasonably identifiable as your SSN, then write SSN for that portion of the professional license number that is represented by your SSN. (For example, "SSN", "12-SSN-345" or "1234-SSN" (last 6 digits)). Attach additional pages if the space provided is insufficient

Organization/Issuer of License Producer's License Address Room 1209, Strawberry Square

City Harrisburg State/Province PA Country USA Postal Code 17120

License Type Annuity - PA License # 365837 Date Issued (MM/YY) 9/26/06

Date Expired (MM/YY) Not applicable Reason for Termination None

Non-insurance Regulatory Phone Number (if known None

Organization/Issuer of License Producer's License Address Room 1209, Strawberry Square

City Harrisburg State/Province PA Country USA Postal Code 17120

License Type Casualty/Accident & Health License # 365837 Date Issued (MM/YY) 09/26/06

Date Expired (MM/YY) Not applicable Reason for Termination None

Non-insurance Regulatory Phone Number (if known None

11. In responding to the following, if the record has been sealed or expunged, and the affiant has personally verified that the record was sealed or expunged, an affiant may respond "no" to the question. Have you ever:

a. Been refused an occupational, professional, or vocational license or permit by any regulatory authority, or any public administrative, or governmental licensing agency?
No

b. Had any occupational, professional, or vocational license or permit you hold or have held, been subject to any judicial, administrative, regulatory, or disciplinary action?
No

c. Been placed on probation or had a fine levied against you or your occupational, professional, or vocational license or permit in any judicial, administrative, regulatory, or disciplinary action?
No

d. Been charged with, or indicted for, any criminal offense(s) other than civil traffic offenses? No

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e. Pled guilty, or nolo contendere, or been convicted of, any criminal offense(s) other than civil traffic offenses?
No

f. Had adjudication of guilt withheld, had a sentence imposed or suspended, had pronouncement of a sentence suspended, or been pardoned, fined, or placed on probation, for any criminal offense(s) other than civil traffic offenses? No

g. Been subject to a cease and desist letter or order, or enjoined, either temporarily or permanently, in any judicial, administrative, regulatory, or disciplinary action, from violating any federal, state law or law of another country regulating the business of insurance, securities or banking, or from carrying out any particular practice or practices in the course of the business of insurance, securities or banking? No

h. Been, within the last ten (10) years, a party to any civil action involving dishonesty, breach of trust, or a financial dispute? No

i. Had a finding made by the Comptroller of any state or the Federal Government that you have violated any provisions of small loan laws, banking or trust company laws, or credit union laws, or that you have violated any rule or regulation lawfully made by the Comptroller of any state or the Federal Government? No

j. Had a lien or foreclosure action filed against you or any entity while you were associated with that entity?
No

If the response to any question above is answered "Yes", please provide details including dates, locations, disposition, etc. Attach a copy of the complaint and filed adjudication or settlement as appropriate.

None

12. List any entity subject to regulation by an insurance regulatory authority that you control directly or indirectly. The term "control" (including the terms "controlling," "controlled by" and "under common control with") means the possession, direct or indirect, of the power to direct or cause the direction of the management and policies of a person, whether through the ownership of voting securities, by contract other than a commercial contract for goods or non-management services, or otherwise, unless the power is the result of an official position with or corporate office held by the person. Control shall be presumed to exist if any person, directly or indirectly, owns, controls, holds with the power to vote, or holds proxies representing, ten percent (10%) or more of the voting securities of any other person. None

If any of the stock is pledged or hypothecated in any way, give details. None

13. Do [Will] you or members of your immediate family individually or cumulatively subscribe to or own, beneficially or of record, 10% or more of the outstanding shares of stock of any entity subject to regulation by an insurance regulatory authority, or its affiliates? An "affiliate" of, or person "affiliated" with, a specific person, is a person that directly, or indirectly through one or more intermediaries, controls, or is controlled by, or is under common control with, the person specified. If the answer is "Yes", please identify the company or companies in which the cumulative stock holdings represent 10% or more of the outstanding voting securities.
No

If any of the shares of stock are pledged or hypothecated in any way, give details.

None

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Applicant Name (Company) Highmark Inc.

NAIC No. 54771
FEIN: 23-1294723

14. Have you ever been adjudged a bankrupt? No If yes, provide details None

15. To your knowledge has any company or entity for which you were an officer or director, trustee, investment committee member, key management employee or controlling stockholder, had any of the following events occur while you served in such capacity? If yes, please indicate and give details. When responding to questions (b) and (c) affiant should also include any events within twelve (12) months after his or her departure from the entity.

a. Been refused a permit, license, or certificate of authority by any regulatory authority, or Governmental-licensing agency? No

b. Had its permit, license, or certificate of authority suspended, revoked, canceled, non-renewed, or subjected to any judicial, administrative, regulatory, or disciplinary action (including rehabilitation, liquidation, receivership, conservatorship, federal bankruptcy proceeding, state insolvency, supervision or any other similar proceeding)? No

c. Been placed on probation or had a fine levied against it or against its permit, license, or certificate of authority in any civil, criminal, administrative, regulatory, or disciplinary action? Yes – See Attachment

Note: If an affiant has any doubt about the accuracy of an answer, the question should be answered in the positive and an explanation provided.

Dated and signed this 25 day of Oct 2010 at Highmark Inc. I hereby certify under penalty of perjury that I am acting on my own behalf, and that the foregoing statements are true and correct to the best of my knowledge and belief.

Deborah L Rice
(Signature of Affiant)

State of Pennsylvania County of Allegheny

The foregoing instrument was acknowledged before me this 25th day of October, 2010 By Deborah Lynn Rice, and:

☑ who is personally known to me, or

☐ who produced the following identification: _____

[SEAL]

COMMONWEALTH OF PENNSYLVANIA
Notarial Seal
Patricia F. Woltjen, Notary Public
City of Pittsburgh, Allegheny County
My Commission Expires Sept. 5, 2011
Member, Pennsylvania Association of Notaries

Patricia F. Woltjen
Notary Public

Patricia F. Woltjen
Printed Notary Name

9-5-11
My Commission Expires

Applicant Name (Company) Highmark Inc.

NAIC No. 54771
FEIN: 23-1294723

**BIOGRAPHICAL AFFIDAVIT**
**Supplemental Personal Information**

**(Print or Type)**

To the extent permitted by law, this affidavit will be kept confidential by the state insurance regulatory authority.

Full Name, Address, and telephone number of the present or proposed entity under which this biographical statement is being required (Do Not Use Group Names).

Highmark Inc.

120 Fifth Avenue

Pittsburgh, PA 15222 Phone: 412-544-7000

1. Affiant's Full Name (Initials Not Acceptable). Deborah Lynn Rice

2. Have you ever used any other name including nickname, maiden name or aliases? Yes If yes, give the reason if any, if none indicate such, and provide the full name(s) and date(s) used.

| Beginning/Ending Date(s) Used (MM/YY) | Name(s) | Reason (If None, indicate such) |
|---|---|---|
| 1963 - 1982 | Deborah Lynn Removchik | Maiden Name |
| 1982 - 1993 | Deborah Lynn Kitchen | Marriage |
| 1994 - Present | Deborah Lynn Rice | Marriage |
| - | | |
| - | | |
| - | | |
| - | | |
| - | | |
| - | | |

Note: Dates provided in response to this question may be approximate, except for current address. Parties using this form understand that there could be an overlap of dates when transitioning from one name to another.

3. Affiant's Social Security Number [redacted]

4. Government Identification Number if not a U.S. Citizen None

5. Foreign Student ID# (if applicable) None

6. Date of Birth: (MM/DD/YY) 4/29/63 Place of Birth: City McKeesport
State/Province PA Country USA

7 Name of Affiant's Spouse (if applicable) [redacted]

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Applicant Name (Company) Highmark Inc.

NAIC No. 54771
FEIN: 23-1294723

8. List your residences for the last ten (10) years starting with your current address, giving:

| Beginning/Ending Dates (MM/YY) | Address | City | State/ Province | Country | Postal Code |
|---|---|---|---|---|---|
| 6/1/08 - Present | [redacted] | | PA | USA | [redacted] |
| 08/01 – 6/08 | 1313 Samantha Way | North Huntington | PA | USA | 15642 |
| 06/95 – 8/01 | 104 Newman Circle | North Versailles | PA | USA | 15137 |

Note: Dates provided in response to this question may be approximate. Parties using this form understand that there could be an overlap of dates when transitioning from one name to another.

Dated and signed this 25 day of Oct, 20 10 at Highmark Inc. I hereby certify under penalty of perjury that I am acting on my own behalf, and that the foregoing statements are true and correct to the best of my knowledge and belief.

Deborah Rice
(Signature of Affiant)

State of Pennsylvania County of Allegheny

The foregoing instrument was acknowledged before me this 25th day of October, 20 10 By Deborah Lynn Rice, and:

☑ who is personally known to me, or

☐ who produced the following identification: _____

[SEAL]

COMMONWEALTH OF PENNSYLVANIA
Notarial Seal
Patricia F. Woltjen, Notary Public
City of Pittsburgh, Allegheny County
My Commission Expires Sept. 5, 2011
Member, Pennsylvania Association of Notaries

Patricia F. Woltjen
Notary Public

Patricia F. Woltjen
Printed Notary Name

9-5-11
My Commission Expires

Applicant Name (Company) Highmark Inc.

NAIC No. 54771
FEIN: 23-1294723

**DISCLOSURE AND AUTHORIZATION CONCERNING BACKGROUND REPORTS (*All states except California, Minnesota and Oklahoma)***

This Disclosure and Authorization is provided to you in connection with pending or future application(s) of Highmark Inc. ("Company") for licensure or a permit to organize ("Application") with a department of insurance in one or more states within the United States. Company desires to procure a consumer or investigative consumer report (or both)("Background Reports") regarding your background for review by a department of insurance in any state where Company pursues an Application during the term of your functioning as, or seeking to function as, an officer, member of the board of directors or other management representative ("Affiant") of Company or of any business entities affiliated with Company ("Term of Affiliation") for which a Background Report is required by a department of insurance reviewing any Application. Background Reports requested pursuant to your authorization below may contain information bearing on your character, general reputation, personal characteristics, mode of living and credit standing. The purpose of such Background Reports will be to evaluate the Application and your background as it pertains thereto. To the extent required by law, the Background Reports procured under this Disclosure and Authorization will be maintained as confidential.

You may obtain copies of any Background Reports about you from the consumer reporting agency ("CRA") that produces them. You may also request more information about the nature and scope of such reports by submitting a written request to Company. To obtain contact information regarding CRA or to submit a written request for more information, contact Carrie Pecht, Highmark Inc., 1800 Center Street, Camp Hill, PA 17089 Phone: 717-302-4226.

Attached for your information is a "Summary of Your Rights Under the Fair Credit Reporting Act."

**AUTHORIZATION:** I am currently an Affiant of Company as defined above. I have read and understand the above Disclosure and by my signature below, I consent to the release of Background Reports to a department of insurance in any state where Company files or intends to file an Application, and to the Company, for purposes of investigating and reviewing such Application and my status as an Affiant. I authorize all third parties who are asked to provide information concerning me to cooperate fully by providing the requested information to CRA retained by Company for purposes of the foregoing Background Reports, except records that have been erased or expunged in accordance with law.

I understand that I may revoke this Authorization at any time by delivering a written revocation to Company and that Company will, in that event, forward such revocation promptly to any CRA that either prepared or is preparing Background Reports under this Disclosure and Authorization. This Authorization shall remain in full force and effect until the earlier of (i) the expiration of the Term of Affiliation, (ii) written revocation as described above, or (iii) twelve (12) months following the date of my signature below.

A true copy of this Disclosure and Authorization shall be valid and have the same force and effect as the signed original.

Deborah Lynn Rice, [redacted]
(Printed Full Name and Residence Address)

Deborah L Rice
(Signature)

10/25/10
(Date)

State of Pennsylvania County of Allegheny

The foregoing instrument was acknowledged before me this 26th day of October 20 10 By:

Deborah Lynn Rice, and

☑ who is personally known to me, or

☐ who produced the following identification: _____

[SEAL]

COMMONWEALTH OF PENNSYLVANIA
Notarial Seal
Patricia F. Woltjen, Notary Public
City of Pittsburgh, Allegheny County
My Commission Expires Sept. 5, 2011
Member, Pennsylvania Association of Notaries

Patricia F. Woltjen
Notary Public

Patricia F. Woltjen
Printed Notary Name

9-5-11
My Commission Expires

# Deborah Lynn Rice
## Attachment to Biographical Affidavit

8. In addition to the preceding information, I presently serve, or have served, in the capacities noted opposite each corporation below:

| Corporation | Position Held | Dates |
|---|---|---|
| Industrial Medical Consultants LLC<br>2740 Smallman Street, Ste. 300<br>Pittsburgh, PA 15222 | Board of Managers | 3/13/07 – 5/28/09 |
| Highmark Casualty Insurance Co.<br>Fifth Avenue Place<br>Pittsburgh, PA 15222 | Director | 4/15/08 – 6/30/10 |
| Highmark West Virginia, Inc.<br>700 Market Square<br>P.O. Box 1948<br>Parkersburg, WV 26101 | Director | 5/14/07 – Present |
| HM Insurance Group<br>Fifth Avenue Place<br>Pittsburgh, PA 15222 | Director | 9/18/07 – 6/30/10 |
| HM Benefits Administrators, Inc.<br>Fifth Avenue Place<br>Pittsburgh, PA 15222 | Director | 9/18/07 – 6/30/10 |
| HM Broker Services, Inc.<br>Fifth Avenue Place<br>Pittsburgh, PA 15222 | Director | 9/18/07 – 6.39.19 |
| HM Casualty Insurance Company<br>Fifth Avenue Place<br>Pittsburgh, PA 15222 | Director | 9/18/07 – 6/30/10 |
| HM Life Insurance Company<br>Fifth Avenue Place<br>Pittsburgh, PA 15222-3099 | Director | 9/18/07 – 6/30/10 |
| HM Life Insurance Company of New York<br>420 Fifth Avenue<br>New York, NY 10018 | Director | 9/18/07 – 9/16/10 |
| Inter-County Health Plan, Inc.<br>720 Blair Mill Road<br>Horsham, PA 19044- 2244 | Director | 10/31/07 - Present |
| Inter-County Hospitalization Plan, Inc.<br>720 Blair Mill Road<br>Horsham, PA 19044-2244 | Director | 10/31/07 - Present |
| Keystone Health Plan West, Inc.<br>120 Fifth Avenue<br>Pittsburgh, PA 15222 | Director<br>Chairperson | 4/1/09 – Present<br>5/29/09 – Present |
| Highmark Senior Resources, Inc.<br>120 Fifth Avenue<br>Pittsburgh, PA 15222 | Director<br>Chairperson | 5/26/09 - Present<br>9/15/09 – Present |

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Applicant Name (Company) Highmark Inc.

NAIC No. 54771
FEIN: 23-1294723

| Corporation | Position Held | | Dates |
|---|---|---|---|
| HM Health Insurance Company<br>120 Fifth Avenue<br>Pittsburgh, PA 15222 | Director<br>Chairperson<br>Executive Vice President, Health Services | | 6/1/09 - 6/30/10<br>9/15/09 – 7/28/10<br>7/28/10 - Present |
| Leadership Pittsburgh<br>425 Sixth Avenue, Ste. 1120<br>Pittsburgh, PA 15219 | Board Member | Term: | 7/1/06 – 7/1/12 |
| The Botanic Gardens of Western PA<br>850 Poplar Street<br>Pittsburgh, PA 15220 | Board Member | Term: | 12/2005 – 6/30/06 |
| United Way of Allegheny County<br>1250 Penn Avenue<br>P.O. Box 735<br>Pittsburgh, PA 15230-0735 | Board Member | Term: | 4/15/08 – 4/15/11 |
| Pittsburgh Symphony Orchestra<br>Heinz Hall<br>600 Penn Avenue<br>Pittsburgh, PA 15222 | Board Member | Term: | 10/31/06 - Present |
| Gwen's Girls<br>7230 McPherson Blvd.<br>Lexington Park, PA 15208 | Board Member | Term: | 6/30/02 – 6/30/06 |
| Pittsburgh Public Theater<br>O'Reilly Theater<br>621 Penn Avenue<br>Pittsburgh, PA 15222 | Board Member | Term: | 9/00 – 9/07 |

15. To your knowledge, has any company or entity for which you were an officer or director, trustee, investment committee member, key management employee, or controlling stockholder, had any of the following events occur while you served in such capacity? If yes, please indicate and give details. When responding to questions (b) and (c), affiant should also include any events within twelve (12) months after his or her departure from the entity.

c. Been placed on probation or had a fine levied against it or against its permit, license, or certificate of authority in any civil, criminal, administrative, regulatory, or disciplinary action? Yes – see below

*Highmark Inc.*

On November 15, 2005, Highmark entered into a Conciliation Agreement with the Federal Election Commission ("FEC"). The Conciliation Agreement was entered to resolve an issue relating to improper corporate contributions in violation of the Federal Election Campaign Act. The violations stemmed from the unauthorized activities of a former employee who caused approximately $54,000 of Highmark corporate funds to be used to defray expenses of fundraising events sponsored by the campaign finance or political action committees of an elected federal official. This conduct was self-disclosed by Highmark to the FEC in March 2004. As part of the Conciliation Agreement, Highmark agreed to pay a civil penalty of $54,078 to the FEC.

Highmark Inc. entered into a Consent Order with the Pennsylvania Insurance Department dated December 23, 2002 regarding allegations of issuance of provider contract forms that had not yet been approved by that Department. A civil penalty of $300,000 was paid at the time in settlement of the allegations. The Consent Order included a cease and desist prohibiting use of unapproved provider contract forms.

Highmark Inc. entered into a Consent Order with the Pennsylvania Insurance Department dated December 26, 2003 as a result of an inadvertent coding error in Highmark Inc.'s claims processing system. Six claims for childhood immunizations were initially denied and, after further review, were later paid. A civil penalty of $3,000 was paid at the time in settlement of the allegations and the coding error was corrected. The Consent Order included a cease and desist provision prohibiting activities of this type subject to the Consent Order.

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Applicant Name (Company) Highmark Inc.

NAIC No. 54771-PA
FEIN: 23-1294723

**BIOGRAPHICAL AFFIDAVIT**

To the extent permitted by law, this affidavit will be kept confidential by the state insurance regulatory authority.

**(Print or Type)**

Full Name, Address and telephone number of the present or proposed entity under which this biographical statement is being required (Do Not Use Group Names).

Highmark Inc.

120 Fifth Avenue

Pittsburgh, PA 15222 Phone: 412-544-7000

In connection with the above-named entity, I herewith make representations and supply information about myself as hereinafter set forth. (Attach addendum or separate sheet if space hereon is insufficient to answer any question fully.) IF ANSWER IS "NO" OR "NONE," SO STATE.

1. Affiant's Full Name (Initials Not Acceptable). Nanette Paden DeTurk

2. a. Are you a citizen of the United States? Yes

   b. Are you a citizen of any other country, if so, what country? None

3. Affiant's Occupation or Profession. Executive Vice President, Chief Administrative and Financial Officer and Treasurer

4. Affiant's business address. 120 Fifth Avenue, Pittsburgh, PA 15222

   Business telephone. [redacted]

5. Education and Training:

| College/ University | City/ State | Dates Attended (MM/YY) | Degree Obtained |
|---|---|---|---|
| Ohio State University | Columbus, OH | 6/80 | BSBA Major-Accounting |

| Graduate Studies: | College/ University | City/ State | Dates Attended (MM/YY) | Degree Obtained |
|---|---|---|---|---|
| Pennsylvania State University | Capital Campus, Harrisburg, PA | | 05/95 | MBA |

| Other Training: Name | City/ State | Dates Attended (MM/YY) | Degree/Certification Obtained |
|---|---|---|---|
| None | | | |

(Note: If affiant attended a foreign school, please provide full address and telephone number of the college/university. If applicable, provide the foreign student Identification Number in the space provided in the Biographical Affidavit Supplemental Information.)

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EXHIBIT
JOINT-54.1

Applicant Name (Company) Highmark Inc.

NAIC No. 54771-PA
FEIN: 23-1294723

6. List of memberships in professional societies and associations.

| Name of Society/Association | Contact Name | Address of Society/Association | Telephone Number of Society/Association |
|---|---|---|---|
| PA Inst. Of Certified Public Accountants | | 1650 Arch Street, 17th Floor, Philadelphia, PA 19103 | 215-496-9272 |
| American Institute of Certified Public Accountants | | 1121 Avenue of the Americas, NY, NY 10036 | 212-596-6200 |

7. Present or proposed position with the applicant entity. Officer

8. List complete employment record for the past twenty (20) years, whether compensated or otherwise (up to and including present jobs, positions, partnerships, owner of an entity, administrator, manager, operator, directorates or officerships). Please list the most recent first. Attach additional pages if the space provided is insufficient. It is only necessary to provide telephone numbers and supervisory information for the past ten (10) years.

Beginning/Ending
Dates (MM/YY) 03/06 – Present Employer's Name Highmark Inc.

Address 120 Fifth Avenue City Pittsburgh State/Province PA

Country USA Postal Code 15222 Phone [redacted] Offices/Positions Held Ex. V.P., Chief Administrative and Financial Officer and Treasurer

Supervisor / Contact [redacted]

Beginning/Ending
Dates (MM/YY) 08/93 – 03/06 Employer's Name Highmark Inc.

Address 120 Fifth Avenue City Pittsburgh State/Province PA

Country USA Postal Code 15222 Phone 412-544-8322 Offices/Positions Held Sr. V.P., Finance & Corp. Controller

Supervisor / Contact Robert C. Gray

Beginning/Ending
Dates (MM/YY) 04/92 - 08/93 Employer's Name The Patriot Group

Address Linglestown Road City Harrisburg State/Province PA

Country USA Postal Code 17110 Phone None Offices/Positions Held VP and CFO

Supervisor / Contact Company no longer exists

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Applicant Name (Company) Highmark Inc.

NAIC No. 54771-PA
FEIN: 23-1294723

Beginning/Ending Dates (MM/YY) 03/91 – 04/92 Employer's Name Summit National Life Insurance Company

Address Erin Street City Lancaster State/Province PA

Country USA Postal Code 17601 Phone 717-396-8511 Offices/Positions Held Controller

Supervisor / Contact Company no longer exists

Please see attachment for additional information

9. a. Have you ever been in a position which required a fidelity bond? Yes. All employees, directors and officers of Highmark and its subsidiary corporations are covered under a fidelity policy, subject to certain policy terms, limits, conditions and exclusions. If any claims were made on the bond, give details. None

   b. Have you ever been denied an individual or position schedule fidelity bond, or had a bond canceled or revoked? If yes, give details. No

10. List any professional, occupational and vocational licenses (including licenses to sell securities) issued by any public or governmental licensing agency or regulatory authority or licensing authority that you presently hold or have held in the past. For any non-insurance regulatory issuer, identify and provide the name, address and telephone number of the licensing authority or regulatory body having jurisdiction over the license (s) issued.. If your professional license number is your Social Security Number (SSN) or embeds your SSN or any sequence of more than five numbers that are reasonably identifiable as your SSN, then write SSN for that portion of the professional license number that is represented by your SSN. (For example, "SSN", "12-SSN-345" or "1234-SSN" (last 6 digits)). Attach additional pages if the space provided is insufficient

See Attached for Additional Information

Organization/Issuer of License Ohio Board of Accountancy Address 77 South High Street, 18th Floor

City Columbus State/Province Ohio Country USA Postal Code 43215

License Type CPA License License # 04-3-15109 Date Issued (MM/YY) 10/82

Date Expired (MM/YY) 12/2007 Reason for Termination No longer needed

Non-insurance Regulatory Phone Number (if known) 614-466-4135

Organization /Issuer of License PA Board of Accountancy Address P.O. Box 2649

City Harrisburg State/Province PA Country USA Postal Code 17105

License Type CPA LicenseLicense # CA028824R Date Issued (MM/YY) 01/90

Date Expired (MM/YY) N/A Reason for Termination N/A

Non-insurance Regulatory Phone Number (if known) 717-787-8503

11. In responding to the following, if the record has been sealed or expunged, and the affiant has personally verified that the record was sealed or expunged, an affiant may respond "no" to the question. Have you ever:

   a. Been refused an occupational, professional, or vocational license or permit by any regulatory authority, or any public administrative, or governmental licensing agency?
   No

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b. Had any occupational, professional, or vocational license or permit you hold or have held, been subject to any judicial, administrative, regulatory, or disciplinary action?
No

c. Been placed on probation or had a fine levied against you or your occupational, professional, or vocational license or permit in any judicial, administrative, regulatory, or disciplinary action? No

d. Been charged with, or indicted for, any criminal offense(s) other than civil traffic offenses? No

e. Pled guilty, or nolo contendere, or been convicted of, any criminal offense(s) other than civil traffic offenses?
No

f. Had adjudication of guilt withheld, had a sentence imposed or suspended, had pronouncement of a sentence suspended, or been pardoned, fined, or placed on probation, for any criminal offense(s) other than civil traffic offenses? No

g. Been subject to a cease and desist letter or order, or enjoined, either temporarily or permanently, in any judicial, administrative, regulatory, or disciplinary action, from violating any federal, state law or law of another country regulating the business of insurance, securities or banking, or from carrying out any particular practice or practices in the course of the business of insurance, securities or banking? No

h. Been, within the last ten (10) years, a party to any civil action involving dishonesty, breach of trust, or a financial dispute? No

i. Had a finding made by the Comptroller of any state or the Federal Government that you have violated any provisions of small loan laws, banking or trust company laws, or credit union laws, or that you have violated any rule or regulation lawfully made by the Comptroller of any state or the Federal Government? No

j. Had a lien or foreclosure action filed against you or any entity while you were associated with that entity?
No

If the response to any question above is answered "Yes", please provide details including dates, locations, disposition, etc. Attach a copy of the complaint and filed adjudication or settlement as appropriate.

Not applicable

12. List any entity subject to regulation by an insurance regulatory authority that you control directly or indirectly. The term "control" (including the terms "controlling," "controlled by" and "under common control with") means the possession, direct or indirect, of the power to direct or cause the direction of the management and policies of a person, whether through the ownership of voting securities, by contract other than a commercial contract for goods or non-management services, or otherwise, unless the power is the result of an official position with or corporate office held by the person. Control shall be presumed to exist if any person, directly or indirectly, owns, controls, holds with the power to vote, or holds proxies representing, ten percent (10%) or more of the voting securities of any other person. None

If any of the stock is pledged or hypothecated in any way, give details. Not applicable

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13. Do [Will] you or members of your immediate family individually or cumulatively subscribe to or own, beneficially or of record, 10% or more of the outstanding shares of stock of any entity subject to regulation by an insurance regulatory authority, or its affiliates? An "affiliate" of, or person "affiliated" with, a specific person, is a person that directly, or indirectly through one or more intermediaries, controls, or is controlled by, or is under common control with, the person specified. If the answer is "Yes", please identify the company or companies in which the cumulative stock holdings represent 10% or more of the outstanding voting securities.
No

If any of the shares of stock are pledged or hypothecated in any way, give details.

Not applicable

14. Have you ever been adjudged a bankrupt? No If yes, provide details

15. To your knowledge has any company or entity for which you were an officer or director, trustee, investment committee member, key management employee or controlling stockholder, had any of the following events occur while you served in such capacity? If yes, please indicate and give details. When responding to questions (b) and (c) affiant should also include any events within twelve (12) months after his or her departure from the entity.

    a. Been refused a permit, license, or certificate of authority by any regulatory authority, or Governmental-licensing agency? No

    b. Had its permit, license, or certificate of authority suspended, revoked, canceled, non-renewed, or subjected to any judicial, administrative, regulatory, or disciplinary action (including rehabilitation, liquidation, receivership, conservatorship, federal bankruptcy proceeding, state insolvency, supervision or any other similar proceeding)? Yes – See Attached

    c. Been placed on probation or had a fine levied against it or against its permit, license, or certificate of authority in any civil, criminal, administrative, regulatory, or disciplinary action? Yes – see attached

Note: If an affiant has any doubt about the accuracy of an answer, the question should be answered in the positive and an explanation provided.

Dated and signed this 12th day of October 2010 at Pgh Pa I hereby certify under penalty of perjury that I am acting on my own behalf, and that the foregoing statements are true and correct to the best of my knowledge and belief.

Nanette P DeTurk
(Signature of Affiant)

State of Pennsylvania County of Allegheny

The foregoing instrument was acknowledged before me this 12th day of October, 2010 By Nanette Paden DeTurk, and:

☑ who is personally known to me, or

☐ who produced the following identification:

COMMONWEALTH OF PENNSYLVANIA
[SEAL] Notarial Seal
Sara M. Malara, Notary Public
City of Pittsburgh, Allegheny County
My Commission Expires Sept. 12, 2014
Member, Pennsylvania Association of Notaries

Sara M. Malara
Notary Public
SARA M. MALARA
Printed Notary Name
Sept 12, 2014
My Commission Expires

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Applicant Name (Company) Highmark Inc.

NAIC No. 54771-PA
FEIN: 23-1294723

**BIOGRAPHICAL AFFIDAVIT**
**Supplemental Personal Information**

**(Print or Type)**

To the extent permitted by law, this affidavit will be kept confidential by the state insurance regulatory authority.

Full Name, Address, and telephone number of the present or proposed entity under which this biographical statement is being required (Do Not Use Group Names).

Highmark Inc.

120 Fifth Avenue

Pittsburgh, PA 15222

1. Affiant's Full Name (Initials Not Acceptable). Nanette Paden DeTurk

2. Have you ever used any other name including nickname, maiden name or aliases? Yes If yes, give the reason if any, if none indicate such, and provide the full name(s) and date(s) used.

| Beginning/Ending Date(s) Used (MM/YY) | Name(s) | Reason (If None, indicate such) |
|---|---|---|
| 05/1958 - 08/1990 | Nanette Lynn Paden | Maiden Name |
| 08/1990 - 09/2003 | Nanette Paden Kline | Marriage |
| 09/2003 - Present | Nanette Paden DeTurk | Marriage |
| - | | |
| - | | |
| - | | |
| - | | |
| - | | |
| - | | |

Note: Dates provided in response to this question may be approximate, except for current address. Parties using this form understand that there could be an overlap of dates when transitioning from one name to another.

3. Affiant's Social Security Number [redacted]

4. Government Identification Number if not a U.S. Citizen None

5. Foreign Student ID# (if applicable) None

6. Date of Birth: (MM/DD/YY) 05/29/1958 Place of Birth: City Bowling Green
State/Province Ohio Country USA

7 Name of Affiant's Spouse (if applicable) [redacted]

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Applicant Name (Company) Highmark Inc.

NAIC No. 54771-PA
FEIN: 23-1294723

8. List your residences for the last ten (10) years starting with your current address, giving:

| Beginning/Ending Dates (MM/YY) | Address | City | State/ Province | Country | Postal Code |
|---|---|---|---|---|---|
| 01/09 - Present | [redacted] | | SC | USA | [redacted] |
| 05/05 – 01/09 | 198 Pleasant Valley Road | Lancaster | NH | USA | 03584 |
| Secondary Residence 01/10 – Present | [redacted] | | | USA | [redacted] |
| Secondary Residence 3/07 – 01/10 | 881 Thorn Street | Sewickley | PA | USA | 15143 |
| Secondary Residence 05/05 – 3/07 | 807 Sonie Drive | Sewickley | PA | USA | 15143 |
| 12/02 – 05/05 | 305 Thorn Street | Sewickley | PA | USA | 15143 |
| 06/99 – 12/02 | 1806 Willow Oak Drive | Wexford | PA | USA | 15090 |
| 01/93 – 06/99 | 4003 Pamay Drive | Mechanicsburg | PA | USA | 17050 |
| 04/90 – 01/93 | 252 Buckfield Drive | Lititz | PA | USA | 17543 |

Note: Dates provided in response to this question may be approximate. Parties using this form understand that there could be an overlap of dates when transitioning from one name to another.

Dated and signed this 12th day of October, 2010 at Pgh Pa I hereby certify under penalty of perjury that I am acting on my own behalf, and that the foregoing statements are true and correct to the best of my knowledge and belief.

Nanette P DeTurk
(Signature of Affiant)

State of Pennsylvania County of Allegheny

The foregoing instrument was acknowledged before me this 12th day of October, 2010 By Nanette Paden DeTurk, and:

☑ who is personally known to me, or

☐ who produced the following identification: _____

COMMONWEALTH OF PENNSYLVANIA
Notarial Seal
Sara M. Malara, Notary Public
[SEAL] City of Pittsburgh, Allegheny County
My Commission Expires Sept. 12, 2014
Member, Pennsylvania Association of Notaries

Sara M Malara
Notary Public

SARA M M ALARA
Printed Notary Name

Sept 12, 2014
My Commission Expires

Applicant Name (Company) Highmark Inc.

NAIC No. 54771-PA
FEIN: 23-1294723

**DISCLOSURE AND AUTHORIZATION CONCERNING BACKGROUND REPORTS (*All states except California, Minnesota and Oklahoma)***

This Disclosure and Authorization is provided to you in connection with pending or future application(s) of Highmark Inc. ("Company") for licensure or a permit to organize ("Application") with a department of insurance in one or more states within the United States. Company desires to procure a consumer or investigative consumer report (or both)("Background Reports") regarding your background for review by a department of insurance in any state where Company pursues an Application during the term of your functioning as, or seeking to function as, an officer, member of the board of directors or other management representative ("Affiant") of Company or of any business entities affiliated with Company ("Term of Affiliation") for which a Background Report is required by a department of insurance reviewing any Application. Background Reports requested pursuant to your authorization below may contain information bearing on your character, general reputation, personal characteristics, mode of living and credit standing. The purpose of such Background Reports will be to evaluate the Application and your background as it pertains thereto. To the extent required by law, the Background Reports procured under this Disclosure and Authorization will be maintained as confidential.

You may obtain copies of any Background Reports about you from the consumer reporting agency ("CRA") that produces them. You may also request more information about the nature and scope of such reports by submitting a written request to Company. To obtain contact information regarding CRA or to submit a written request for more information, contact Carrie J. Pecht, Esq., Highmark Inc., 1800 Center Street, Camp Hill, PA 17089 – Phone: 717-302-4204.

Attached for your information is a "Summary of Your Rights Under the Fair Credit Reporting Act."

**AUTHORIZATION:** I am currently an Affiant of Company as defined above. I have read and understand the above Disclosure and by my signature below, I consent to the release of Background Reports to a department of insurance in any state where Company files or intends to file an Application, and to the Company, for purposes of investigating and reviewing such Application and my status as an Affiant. I authorize all third parties who are asked to provide information concerning me to cooperate fully by providing the requested information to CRA retained by Company for purposes of the foregoing Background Reports, except records that have been erased or expunged in accordance with law.

I understand that I may revoke this Authorization at any time by delivering a written revocation to Company and that Company will, in that event, forward such revocation promptly to any CRA that either prepared or is preparing Background Reports under this Disclosure and Authorization. This Authorization shall remain in full force and effect until the earlier of (i) the expiration of the Term of Affiliation, (ii) written revocation as described above, or (iii) twelve (12) months following the date of my signature below.

A true copy of this Disclosure and Authorization shall be valid and have the same force and effect as the signed original.

Nanette Paden DeTurk, [redacted]

(Printed Full Name and Residence Address)

Nanette PDeTurk
(Signature)

10/12/2010
(Date)

State of Pennsylvania County of Allegheny

The foregoing instrument was acknowledged before me this 12th day of October 2010 By

Nanette Paden DeTurk, and

☑ who is personally known to me, or

☐ who produced the following identification: _____

[SEAL]
COMMONWEALTH OF PENNSYLVANIA
Notarial Seal
Sara M. Malara, Notary Public
City of Pittsburgh, Allegheny County
My Commission Expires Sept. 12, 2014
Member, Pennsylvania Association of Notaries

Sara M Malara
Notary Public

SARA M MALARA
Printed Notary Name

Sept 12, 2014
My Commission Expires

**Nanette P. DeTurk**
**Attachment to**
**Biographical Affidavit**

In addition to the preceding information, I serve or have served in the capacities noted opposite the corporations listed below:

| Corporation | Position | Dates Served |
|---|---|---|
| Highmark Ventures, Inc.<br>120 Fifth Avenue<br>Pittsburgh, PA 15222 | President<br>Director | 5/11/06-Present<br>5/11/06-08/10 |
| Don Mayes and Associates, Inc.<br>4401 Deer Path Road<br>Harrisburg, PA 17110 | Director | 03/05/01-01/21/05 |
| United Concordia Companies, Inc.<br>4401 Deer Path Road<br>Harrisburg, PA 17110 | Director | 5/23/07 – 6/30/10 |
| JustDental of Delmarva, Inc.<br>1220 B East Joppa Road, Suite 421<br>Towson, MD 21286-5811 | Director | 03/05/01-05/26/04 |
| MIDA Dental Plans of California, Inc.<br>21700 Oxnard Street, Suite 500<br>Woodland Hills, CA 91367 | Director | 03/05/01-05/15/00 |
| United Concordia Dental Plans, Inc.<br>309 International Circle, Suite 130<br>Hunt Valley, MD 21030 | Director | 03/05/01-12/12/07 |
| United Concordia Dental Corporation<br>Of Alabama<br>400 Vestavia Parkway, Ste. 205<br>Birmingham, AL 35216 | Director | 2/26/02 – 12/12/07 |
| United Concordia Dental Plans<br>of California, Inc.<br>21700 Oxnard Street, Suite 500<br>Woodland Hills, CA 91367 | Director | 03/05/01-12/12/07 |
| United Concordia Dental Plans<br>of Delaware, Inc.<br>309 International Circle, Suite 130<br>Hunt Valley, MD 21030 | Director | 03/05/01-12/12/07 |

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| Corporation | Position | Dates Served |
|---|---|---|
| United Concordia Dental Plans of Florida, Inc.<br>HQ Westshore Center<br>2202 North Westshore Blvd., Ste. 200<br>Tampa, FL 33607 | Director | 03/05/01-12/12/07 |
| United Concordia Dental Plans of Illinois, Inc.<br>801 Adlai Stevenson Drive<br>Springfield, IL 62703 | Director | 03/05/01-12/12/07 |
| United Concordia Dental Plans of Kentucky, Inc.<br>421 West Main Street<br>Frankfort, KY 40601 | Director | 03/05/01-12/12/07 |
| United Concordia Dental Plans of Pennsylvania, Inc.<br>4401 Deer Path Road<br>Harrisburg, PA 17110 | Director | 03/05/01-12/12/07 |
| United Concordia Dental Plans of Texas, Inc.<br>8214 Westchester Drive, Suite 600<br>Dallas, TX 75225 | Director | 03/05/01-12/12/07 |
| United Concordia Dental Plans of Washington, Inc.<br>520 Pike Street<br>Seattle, WA 98101 | Director | 03/05/01-12/12/07 |
| United Concordia Insurance Company<br>2198 East Camelback Road, Suite 260<br>Phoenix, AZ 85016 | Director | 03/05/01-12/12/07 |
| United Concordia Life and Health Insurance Company<br>4401 Deer Path Road<br>Harrisburg, PA 17110 | Director | 03/05/01-12/12/07 |
| United Concordia Insurance Company of New York<br>159 Express Street<br>Plainview, NY 11803 | Director | 03/18/03-12/12/07 |

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| Corporation | Position | Dates Served |
|---|---|---|
| United Concordia Services, Inc.<br>4775 Indian School Road, NE<br>Albuquerque, NM 87109 | Director | 09/28/04-12/12/07 |
| United Concordia Dental Plans<br>of the Midwest, Inc.<br>3250 West Big Beaver, Ste. 327<br>Troy, MI 48084 | Director | 03/04/05-6/30/10 |
| KV Holdings, Inc.<br>1800 Center Street<br>Camp Hill, PA 17089 | Director<br>Treasurer | 6/1/98 – 4/9/09<br>6/1/98 – 4/9/09 |
| Keystone Health Plan Central, Inc.<br>PO Box 898812<br>Camp Hill, PA 17089-8812 | Director | 06/98-06/99 |
| Highmark Health Ventures Investment<br>Fund, LP<br>HHV Management, Inc.<br>Forbes Tower, Suite 10097<br>200 Lothrop Street<br>Pittsburgh, PA 15213 | Committee Member | 12/31/02-08/30/06 |
| VivoQuest, Inc.<br>711 Executive Boulevard<br>Valley Cottage, NY 10989 | Director | 02/01/03-Present |
| Revivicor Holdings, Inc.<br>1700 Kraft Drive<br>Blacksburg, VA 24060 | Director<br>Treasurer | 04/01/03-8/06<br>04/01/03-8/06 |
| Revivicor, Inc.<br>1700 Kraft Drive<br>Blacksburg, VA 24060 | Director | 04/01/03-8/06 |
| Immunosite<br>605 William Pitt Way<br>Building B-3<br>Pittsburgh, PA 15238 | Director | 04/03-12/04 |
| HVHC Inc.<br>1013 Centre Road<br>Wilmington, DE 19805 | Chairman<br>President & CEO<br>Director<br>Treasurer | 1/2/08 - Present<br>1/2/08 – 7/1/08<br>02/17/05-Present<br>02/17/05-09/1/06 |

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| Corporation | Position | Dates Served |
|---|---|---|
| DVSC, Inc.<br>1800 Center Street<br>Camp Hill, PA 17089 | Director | 02/17/05- 8/4/08 |
| Davis Vision, Inc.<br>159 Express Street<br>Plainview, NY 11803 | Chairperson<br>Director | 1/3/08 – 7/1/08<br>02/17/05-Present |
| Davis Vision IPA, Inc.<br>159 Express Street<br>Plainview, NY 11803 | Director | 02/17/05- 8/4/08 |
| Empire Vision Center, Inc.<br>2921 Erie Boulevard East<br>Syracuse, NY 13324 | Director | 02/17/05- 8/4/08 |
| Davis Vision of Nevada, Inc.<br>333 South Maryland Parkway<br>Las Vegas, NV 89103 | Director | 02/17/05-12/31/07 |
| Davis Vision of Michigan, Inc.<br>3250 West Big Beaver, Ste. 327<br>Troy, MI 48084 | Director | 02/17/05-11/17/06 |
| Viva Optique, Inc.<br>3140 Route 22 West<br>Somerville, NJ 08676 | Director | 02/17/05-Present |
| Viva International, Inc.<br>3140 Route 22 West<br>Somerville, NJ 08676 | Director | 07/24/06 – 8/4/08 |
| Viva IP Corp.<br>3140 Route 22 West<br>Somerville, NJ 08676 | Director | 07/24/06 – 8/4/08 |
| Viva Europa, Inc.<br>3140 Route 22 West<br>Somerville, NJ 08676 | Director | 1/1/08 – 8/4/08 |
| Miracle Optics, Inc.<br>709 Brea Canyon Rd., Ste. 7<br>Walnut, CA 91789 | Director | 07/24/06 – 8/4/08 |
| ECCA Holdings Corporation<br>2711 Centerville Road, Ste. 400<br>Wilmington, DE 19808 | Director<br>Treasurer | 08/01/06 – Present<br>08/01/06 – 5/12/08 |

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| Corporation | Position | Dates Served |
|---|---|---|
| Eye Care Centers of America, Inc.<br>11103 West Avenue<br>San Antonio, TX 78213 | Chairperson<br>Director | 1/3/08 – 7/1/08<br>08/01/06 – Present |
| HealthGuard of Lancaster, Inc.<br>1800 Center Street<br>Camp Hill, PA 17011 | Treasurer | 08/02/04-Present |
| HealthGuard Management Services Company<br>1800 Center Street<br>Camp Hill, PA 17011 | Treasurer | 08/04-10/21/08 |
| Keystone Health Plan West<br>120 Fifth Avenue<br>Pittsburgh, PA 15222 | Exec. Vice Pres.<br>Treasurer & CFO<br>Senior Vice Pres.<br>Director | 03/30/06-12/5/07<br>03/30/06-12/5/07<br>04/29/04-03/30/06<br>5/11/06-12/5/07 |
| Western PA Chapter of Juvenile Diabetes Research Foundations<br>Western PA Chapter Convention Tower<br>960 Penn Avenue, Ste. 1000<br>Pittsburgh, PA 15222 | Director | 01/05-Present |
| Sharon Primary Care, Inc.<br>120 Fifth Avenue<br>Pittsburgh, PA 15222 | Director | 01/03/05-8/30/05 |
| JEA, Inc.<br>120 Fifth Avenue<br>Pittsburgh, PA 15222 | Director<br>Treasurer<br>Director | 1/27/00 – 12/3/07<br>1/27/00 – 12/3/07<br>4/26/10 - Present |
| Standard Property Corp.<br>120 Fifth Avenue<br>Pittsburgh, PA 15222 | Director<br>Treasurer<br>Director | 1/27/00 – 12/3/07<br>1/27/00 – 12/3/07<br>4/26/10 - Present |
| Inter-County Health Plan, Inc.<br>720 Blair Mill Road<br>Horsham, PA 19044 | Director | 01/28/05-11/12/07 |
| Inter-County Hospitalization Plan, Inc.<br>720 Blair Mill Road<br>Horsham, PA 19044 | Director | 01/28/05-11/12/07 |

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| Corporation | Position | Dates Served |
|---|---|---|
| HM Health Insurance Company<br>120 Fifth Avenue<br>Pittsburgh, PA 15222 | Director<br>Treasurer & CFO<br>Assistant Treasurer<br>EVP, Chief Administrative & Financial Officer & Treasurer | 3/13/06-12/4/07<br>3/13/06-12/4/07<br>10/17/05 – 3/27/06<br>7/28/10 - Present |
| Highmark Senior Resources Inc.<br>120 Fifth Avenue<br>Pittsburgh, PA 15222 | Treasurer & CFO<br>Exe. V.P.<br>Director | 3/13/06-12/4/07<br>3/13/06-12/4/07<br>6/2/06-12/4/07 |
| Highmark West Virginia Inc.<br>700 Market Square<br>P.O. Box 1948<br>Parkersburg, WV 26101 | Director | 5/11/06-Present |
| Parker Benefits, Inc.<br>700 Market Street<br>P.O. Box 1948<br>Parkersburg, WV 26101 | Director | 5/1/07 – 7/1/09 |
| Gateway Health Plan, L.P.<br>US Steel Tower, Floor 41<br>600 Grant Street<br>Pittsburgh, PA 15219 | Executive Committee | 6/22/06 – Present |
| Gateway Health Plan of Ohio, Inc.<br>US Steel Tower, Floor 41<br>600 Grant Street<br>Pittsburgh, PA 15219 | Director | 6/22/06 – Present |
| Employee Benefit Data Services Company (eBDS)<br>One Gateway Center, 12th Floor<br>Pittsburgh, PA 15222 | Director<br>Treasurer | 08/01/06 – 12/13/07<br>08/01/06 – 12/13/07 |
| Union Benefit Management, Inc.<br>One Gateway Center, 12th Floor<br>Pittsburgh, PA 15222 | Director<br>Treasurer | 08/01/06 – 12/5/07<br>08/01/06 – 12/5/07 |
| Highmark Foundation<br>120 Fifth Avenue<br>Pittsburgh, PA 15222-3099 | Director | 07/21/07 – 12/6/07 |
| KHP Inc.<br>100 Senate Avenue<br>Camp Hill, PA 17011 | Director, President & Treasurer | 11/14/08 – Present |

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**Nanette P. DeTurk**
**Attachment to**
**Biographical Affidavit**

8. List complete employment record for the past twenty (20) years, whether compensated or otherwise (up to and including present jobs, positions, partnerships, owner of an entity, administrator, manager, operator, directorates, or officerships). Please list the most recent first. Attach additional pages if the space provided is insufficient.

Continued...

Beginning/Ending
Dates (MM/YY) 11/89 - 03/91 Employer's Name Price Waterhouse and Company

Address 17th Street City Philadelphia State/Province PA

Country USA Postal Code 19103 Phone 215-575-5000 Offices/Positions Held Senior Manager

Supervisor/Contact Contact Human Resources Dept.

10. List any professional, occupational and vocational licenses (including licenses to sell securities) issued by any public or governmental licensing agency or regulatory authority or licensing authority that you presently hold or have held in the past. For any non-insurance regulatory issuer, identify and provide the name, address and telephone number of the licensing authority or regulatory body having jurisdiction over the license(s) issued. Attach additional pages if the space provided is insufficient.

Organization/Issuer of License NJ Board of Accountancy Address P.O. Box 45000

City Newark State/Province NJ Country USA Postal Code 07101

License Type CPA License License # Date Issued (MM/YY) 10/86

Date Expired (MM/YY) 01/90 Reason for Termination Moved

Non-insurance regulatory Phone Number (if known) 973-504-6380

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**Nanette P. DeTurk**
**Attachment to**
**Biographical Affidavit**

15. To your knowledge, has any company or entity for which you were an officer or director, trustee, investment committee member, key management employee, or controlling stockholder, had any of the following events occur while you served in such capacity? If yes, please indicate and give details. When responding to questions (b) and (c), affiant should also include any events within twelve (12) months after his or her departure from the entity.

b. Had its permit, license, or certificate of authority suspended, revoked, canceled, non-renewed, or subjected to any judicial, administrative, regulatory, or disciplinary action (including rehabilitation, liquidation, receivership, conservatorship, federal bankruptcy proceeding, state insolvency, supervision or any other similar proceeding)? Yes – see below

***Davis Vision, Inc. License Revocations:***
Certain certificates of authority held by Davis Vision, Inc. were revoked by the states of Maryland, Arkansas and Oklahoma due primarily to administrative errors related to tax, annual report or other required filings. The revocations had no material adverse effect on the business and all certificates of authority were subsequently reinstated.

c. Been placed on probation or had a fine levied against it or against its permit, license, or certificate of authority in any civil, criminal, administrative, regulatory, or disciplinary action? Yes – please see below

***HealthGuard of Lancaster, Inc.***
On November 3, 2004, HealthGuard of Lancaster, Inc. entered into a Consent Order issued by the Deputy Insurance Commissioner of the Commonwealth of Pennsylvania, arising out of a follow-up review required as a condition of an April 20, 2004 Consent Order which revealed Act 159 violations. In June 2004, HealthGuard reported numerous additional group premium rates that were not compliant with Act 159 requirements. As a result, the Company agreed to the Consent Order and paid a civil fine in the amount of $1.6 million to settle the matter. HealthGuard has also agreed to offer transitional rates that are subject to approval by the Insurance Department, which will provide relief that could be valued up to $10.1 million to affected groups which were undercharged. The terms of the Consent Order contained a Cease and Desist from engaging in the described activities.

***United Concordia Life and Health Insurance Company***
Case No. MIA-2008-09-015
MIA File No. 15608-A-2008-SSJ-C
On September 10, 2008, the Maryland Insurance Administration entered an Order taking disciplinary action against the Company arising out of a complaint proceeding alleging improper denial of payment for restoration of a crown. The Company authorized payment in accordance with the Order and in full settlement of the action.

***United Concordia Dental Plans of California, Inc.***
In August 2005, United Concordia Dental Plans of California, Inc. was notified by the California Department of Managed Health Care that it had not timely filed annual reports describing the Plan's efforts to deter, detect, investigate, and report fraud to law enforcement agencies for the years 2003 and 2004, by January 31st following each reporting year. The Corporation agreed to payment of an administrative penalty in the amount of $2,500 in settlement of the matter and corrective actions were taken.

***United Concordia Dental Plans, Inc.***
*$50,000 – Commissioner's Case No. MIA-578-11/01 dated November 1, 2001.* United Concordia Dental Plans, Inc. (UCDP) consented, via a Consent Order, to an administrative penalty in the amount of $50,000. The penalty was assessed as the result of a market conduct examination performed by the Maryland Insurance Administration for the period January 1, 1998 through December 31, 2000. The Consent Order also imposed a requirement for UCDP to fund efforts and/or projects designed to educate and assist MD health care consumers concerning their health care rights and responsibilities in an amount up to but not to exceed $50,000. The Consent Order set forth

21 determinations, which the Insurance Administration/Commissioner found to be in violation of Maryland insurance laws and regulations. UCDP paid the $50,000 administrative penalty and implemented procedures to comply with the remainder of the Commissioner's orders within the timeframes prescribed therein.

***JustDental of Delmarva, Inc.***
Settlement Order
Case No. INS020011 dated March 20, 2002.
On March 20, 2002, the State Corporation Commission of the Commonwealth of Virginia issued a Settlement Order arising out of a target market conduct examination performed for the period March 1, 2001 through December 6, 2001. The findings alleged violations of Virginia laws regarding provider contract provisions and claims payment processing procedures. The Company agreed to settlement in the matter and paid a sum of $1,500 to the State Corporation Commission of the Commonwealth of Virginia.

Settlement Order
Case No. INS-2002-01285
On November 21, 2002, the State Corporation Commission of the Commonwealth of Virginia issued a Settlement Order arising out of a market conduct examination performed as of December 31, 2001. The findings alleged violations of Virginia laws regarding provider and member contract and claim administration procedures. The Company agreed to settlement in the matter and paid a sum of $18,000 to the State Corporation Commission of the Commonwealth of Virginia.

Settlement Order
Case No. INS-2003-00001
On January 24, 2003, the State Corporation Commission of the Commonwealth of Virginia issued a Settlement Order arising out an investigation regarding commission payments to unappointed agents. The Company agreed to settlement in the matter and paid a sum of $500 to the State Corporation Commission of the Commonwealth of Virginia.

***United Concordia Insurance Company:***
Arizona: In January 2009, the Arizona Department of Insurance issued a Consent Order arising out of a market conduct examination performed as of June 30, 2006, concluded on August 19, 2008. The findings alleged violations of Arizona insurance laws regarding claims administration procedures. The Company was ordered to Cease and Desist from the violative activities and was required to implement corrective actions which included performing a self-audit and reprocessing any incorrectly denied claims. The Company paid a civil penalty of $30,000 in settlement of the matter.

Nevada: On December 31, 2007, United Concordia Insurance Company was notified by the Nevada Department of Business and Industry that the Company had not filed an Annual Quality of Health Care report in accordance with Nevada law requiring such reports to be filed by March 1 of each year. The Company consented to a fine in the amount of $500 and corrective actions were taken.

Arkansas: On August 13, 2004, United Concordia Insurance Company was notified by the Arkansas Insurance Department that the Company did not remit its annual Financial Regulatory Fee in accordance with Arkansas law requiring such reports to be filed by July 1, 2004. The Company consented to a fine in the amount of $500 and corrective actions were taken.

***Keystone Health Plan Central, Inc.:***
On September 30, 1999, Keystone Health Plan Central, Inc. entered into a consent order with the Insurance Commissioner of the Commonwealth of Pennsylvania, due to violations assessed as the result of a market conduct examination covering the period January 1, 1998 through December 31, 1998, which included a review of the Company's compliance with prompt payment of claims provisions contained in PA Act 68 of 1998 (the Quality Health Care and Accountability and Protection Act) for the period January 1, 1999 through March 31, 1999. The consent order noted violations of Pennsylvania insurance laws and regulations. The terms of the Consent Order

contained a Cease and Desist from engaging in the described activities. The Company agreed to the Consent Order and paid a civil fine in the amount of $65,000, in settlement of the matter.

***Highmark Inc.***

On November 15, 2005, Highmark entered into a Conciliation Agreement with the Federal Election Commission ("FEC"). The Conciliation Agreement was entered to resolve an issue relating to improper corporate contributions in violation of the Federal Election Campaign Act. The violations stemmed from the unauthorized activities of a former employee who caused approximately $54,000 of Highmark corporate funds to be used to defray expenses of fundraising events sponsored by the campaign finance or political action committees of an elected federal official. This conduct was self-disclosed by Highmark to the FEC in March 2004. As part of the Conciliation Agreement, Highmark agreed to pay a civil penalty of $54,078 to the FEC.

Highmark Inc. entered into a Consent Order with the Pennsylvania Insurance Department dated December 23, 2002 regarding allegations of issuance of provider contract forms that had not yet been approved by that Department. A civil penalty of $300,000 was paid at the time in settlement of the allegations. The Consent Order included a cease and desist prohibiting use of unapproved provider contract forms.

Highmark Inc. entered into a Consent Order with the Pennsylvania Insurance Department dated December 26, 2003 as a result of an inadvertent coding error in Highmark Inc.'s claims processing system. Six claims for childhood immunizations were initially denied and, after further review, were later paid. A civil penalty of $3,000 was paid at the time in settlement of the allegations and the coding error was corrected. The Consent Order included a cease and desist provision prohibiting activities of this type subject to the Consent Order.

***HM Health Insurance Company***

Trigon Health and Life Insurance Company (now HM Health Insurance Company) failed to submit a 2003 Annual Certification of Advertisement Report as required by a provision of Nevada Insurance Code that requires insurers to file an Annual Certification of Advertisement Report on or before December 31st of each year. The failure to submit the Report occurred under prior ownership. The Corporation submitted to the Nevada Division of Insurance an executed Consent to Fine, a penalty of $500 and the 2003 Annual Certification of Advertisement Report.

***Davis Vision, Inc.:***

New York: In June 2010, Davis Vision, Inc. was notified by the State of New York Insurance Department that it had not identified the assessment of a fine by the Connecticut Insurance Department within the 30 day timeframe from final date of disposition. The Company entered into a Stipulation which included a fine in the amount of $750.

Connecticut: In December 2008, Davis Vision, Inc. entered an Order with the State of Connecticut Insurance Department arising out of an examination conducted of Davis Vision's utilization review practices in the State of Connecticut covering the period from January 1, 2007 through December 31, 2007. The findings alleged a violation of Connecticut laws regarding timely notice of a utilization review determination and a failure to provide sufficient documentation for regulatory review. The Company admitted to the allegations and consented, via a Complaint, Stipulation and Final Order to an administrative fine in the amount of $2,000. The Company revised its policies and procedures to avoid future recurrences.

New York: In September 2007, Davis Vision, Inc. was notified by the State of New York Insurance Department that it had not identified the assessment of a fine by the Nevada Division of Insurance in 2002 in a renewal application for a life/accident and health license under section 2103(a) of New York insurance law. The Company entered into a Stipulation which included a fine in the amount of $500. The Company implemented corrective action measures to avoid future inadvertent omissions.

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Maine: In September 2006, Davis Vision, Inc. was notified by the State of Maine Bureau of Insurance that it had not disclosed the administrative proceeding to which it was a party with the State of Nevada upon submission of an application to the State of Maine for a Non-Resident Producer Business Entity license. In August 2007, Davis Vision entered into a Consent Agreement and remitted an administrative penalty in the amount of $250, following which the Producer license was issued.

Nevada: In March 2006, Davis Vision, Inc. was notified by the State of Nevada Department of Business and Industry that the Company's annual report required in connection with its third party administrator activities in that state was not timely filed and was incomplete, in violation of Nevada laws governing third party administrators. The Company consented, via a Consent to Fine, to an administrative penalty in the amount of $500.

Nevada: In September 2002, Davis Vision, Inc. was notified by the State of Nevada Department of Business and Industry that the Company had not filed a report stating the total amount of money received and distributed during the preceding fiscal year as required under Nevada law in connection with its third party administrator activities in that state. The company consented, via a Consent to Fine, to an administrative penalty in the amount of $500.

***Empire Vision Center, Inc.***
Massachusetts: Docket No. OP-07-2002
In November 2006, Empire Vision Center, Inc. (Empire) entered into a Consent Agreement with the Commonwealth of Massachusetts, Board of Registration of Optometrists (the Board) arising out of the Board's complaint alleging that Empire had violated Massachusetts General Laws governing the unlicensed practice of optometry, by controlling or directing the actions or decisions of optometrists. Empire agreed to enumerated conditions in the Consent Agreement and paid a fine in the amount of $10,000.

***Eye Care Centers of America***
Illinois (2010): Consent Order dated March 26, 2010 by the State of Illinois, Department of Financial and Professional Regulations, Division of Professional Regulations. On September 28, 2009, the Department of Financial and Professional Regulations filed a complaint against Eye Care Centers of America, Inc. d/b/a Visionworks, in Illinois alleging that an advertisement by Visionworks placed in the Chicago Tribune Newspaper violated Illinois statutes on the unlicensed practice of optometry. Visionworks denied the allegation. However, the parties entered a consent order whereby Visionworks (1) agreed to pay the sum of $10,000 as a civil penalty and (2) agreed to take actions to scrutinize future advertisements that it places in print media for optometric services to eliminate what may be construed as misleading or inaccurate information concerning Illinois law. This matter is resolved.

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Department of Insurance

Exhibit No. 43

Testimony of Martin Alderson Smith

(to be provided)

EXHIBIT
JOINT-55

Department of Insurance

Exhibit No. 44

Testimony of Kenneth Jackson

(to be provided)

EXHIBIT
JOINT-56

Department of Insurance

Exhibit No. 45

Testimony of Linda Sizemore

(to be provided)

EXHIBIT
JOINT-57

# INDEPENDENT NEWSPAPERS, INC.

P. O. Box 7001 • Dover, Delaware • 19903 • 1-800-282-8586

State of Delaware:

County of Kent:

Before me, a Notary Public, for the County and State aforesaid, Edward Dulin, known to me to be such, who being sworn according to law deposes and says that he is President of Independent Newspapers, Inc. / Delmarva, the publisher of **The Delaware State News**, a daily newspaper published at Dover, County of Kent, and State of Delaware, and that the notice, a copy of which is hereto attached, as published in **The Delaware State News** in its issue of December 3-7, 2010.

President
Independent Newspapers, Inc. / Delmarva

Sworn to and subscribed before me this 7th

Day of December A.D. 2010

Janet E. Levy
Notary Public

JANET E. LEVY
COM. EXP.
NOTARY PUBLIC
11-3-2011
STATE OF DELAWARE

EXHIBIT
JOINT-58

**IN RE: THE PROPOSED AFFILIATION OF BCBSD, INC., DOING BUSINESS AS BLUE CROSS BLUE SHIELD OF DELAWARE, WITH HIGHMARK INC.**

**PUBLIC HEARING**
**IDENTIFICATION OF PARTIES IN INTEREST**

Highmark Inc., a Pennsylvania nonprofit corporation, has filed with Insurance Commissioner Karen Weldin Stewart, pursuant to the Commissioner's general regulatory authority under 18 Del. C. § 301 et seq., a proposed plan to affiliate with BCBSD, Inc., a Delaware nonprofit health service corporation. The Hearing Officer, appointed by the Commissioner's Order, dated November 4, 2010, will hold a hearing open to the public to consider the merits of the affiliation proposal, although no hearing date has been established relating to the merits of the proposal.

Any person who seeks to be determined a party in interest to this proceeding must submit to the Delaware Department of Insurance a statement, in writing, providing his or her name; the name of his or her organization, if any; and the name of his or her counsel, if any. The statement must further provide a brief statement explaining why he, she, or the organization which he or she represents. has a significant pecuniary interest in the proceeding, which interest is not adequately represented by an existing party, and the protection of which otherwise will be impaired or impeded unless such person is admitted as a party, and that therefore, pursuant to the Pre-Hearing Order, dated October 20, 2010, such person should be declared a party to this proceeding. The foregoing written statement must be submitted to Linda Sizemore, Director of Company Regulation, at the Delaware Department of Insurance, 841 Silver Lake Boulevard, Dover, DE 19904-2465, no later than 4:00 p.m. Tuesday, December 28, 2010, by mail, hand, parcel service, fax delivery (302-739-2709), or electronic mail (Linda.Sizemore@state.de.us). If delivered by fax or electronic mail to the Delaware Department of Insurance, the original signed document must be received by the Delaware Insurance Department within two (2) days of the transmission. A duplicate submission shall be simultaneously served on counsel for each of the original parties to the proceeding by any one of the following methods: mail, hand, parcel service, fax delivery, or electronic mail, as follows: David S. Swayze, Esquire, attorney for BCBSD, Inc., at Parkowski, Guerke & Swayze, P.A., 800 King Street, Suite 203, Wilmington, DE 19801 (fax: 302-654-3033; email: dswayze@pgslegal.com); Michael Houghton, Esquire, attorney for the Delaware Department of Insurance at Morris, Nichols, Arsht & Tunnell, LLP, 1201 North Market Street, P.O. Box 1347, Wilmington, DE 19899 (fax: 302-658-3989; email: mhoughton@mnat.com); Frederick K. Campbell, Esquire, attorney for Highmark Inc., at Mitchell & Williams, 425 West Capitol Avenue, Suite 1800, Little Rock, AR 72201-3525 (fax: 501-688-8807; email: RCampbell@mwlaw.com); and Timothy P. Mullaney, Sr., Esquire, attorney for the Delaware Department of Justice, at P.O. Box 1227, Dover, DE 19901 (fax: 302-577-6499; email: Tim.Mullaney@state.de.us).

The Hearing Officer will hold a public hearing at the Delaware Department of Insurance Hearing Room, 841 Silver Lake Boulevard, Dover, DE 19904 at 9:30 a.m. on Tuesday, January 18, 2011 to hear argument in support of or in opposition to such requests for party status by the applicant or parties to the proceeding. If necessary, the Hearing Officer may continue such hearing to a date and time to be set by the Hearing Officer. Public Comment at this hearing shall be limited to the party status issue. There will be no opportunity for Public Comment at this hearing on the merits of the affiliation proposal. Public Comment on the merits of the affiliation proposal from any person not afforded party status may be provided in writing or orally at a subsequent public hearing to be scheduled.

Additional information about this matter is available at
http://www.delawareinsurance.gov/departments/bcbs/bcbs.shtml.
372742 DSN 12/3-7/2010