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1. What are the anticipated changes to the administrative, technical, business, operational, or workflow processes when the new standard becomes mandatory for use?
There may be a need to re-contract with our Pharmacy Benefit Managers (PBM's) and software vendors. Re-contracting with Medicaid plans will require an effort from our compliance team. Technical changes between the existing and new versions will need to be defined, coded, and tested. This means resources will need to be dedicated and prioritized over other projects. It also requires development costs that need to be budgeted. Changes of this scale will require training so that all of our pharmacies understand what is changing and what the benefits of the change will be.

2. What are the anticipated benefits to business, operational or workflow processes of implementing this new version of the pharmacy standard?
One of the major benefits within the new standard is a field in the response called "Adjudicated Program Type." This field will be mandatory and will be populated with values such as Medicaid, Medicare, Managed Medicaid, MMP, SPAP, and PACE. As a Long Term Care pharmacy whose payer mix is primarily government funded, this is extremely important to us. In a retail setting, the patient walks in with their prescription card, hands it to the pharmacist, and the pharmacist knows what type of insurance plan they're dealing with. In Long Term Care, we're usually only given a social security #, Medicare #, or a Medicaid #, and we then need to run eligibility checks for Medicare Part D, Managed Medicaid, and commercial insurance. It is a time consuming process to ensure we have proper coverage information for the patient, which can change depending upon the entity that is paying for their stay in the facility. We need to ensure that we have the proper billing information so we know what type of overrides might be allowed and what type of restrictions need to be considered, such as Medicaid being the payer of last resort. We often receive manufacturer sponsored coupons from our patients that are intended to help reduce the burden of cost sharing; however these coupons are not allowed to be used in conjunction with government funded programs. The new adjudicated program type field would allow us identify that a claim was paid by a government program and we could then create system logic to exclude coordination of benefits with coupons when this occurs. Obviously, an approved E1 will give us Medicare Part D information. Version F2 provides enhancements to the E1 response that will provide additional benefit to LTC pharmacies, including Hospice plan names, effective dates, and termination dates, as well as ESRD effective and termination dates. These new informational fields allow a better flow of information about the patient to the pharmacy and thus allow the pharmacy to more accurately bill claims to the proper entity.

Additional benefits that will be useful to all pharmacies are the appearance of new response fields that provide information about allowable plan overrides. The Plan Benefit Override Indicator and Plan Benefit override value communicate this information in the claim response and the pharmacy is able to act upon it without having to place a call to the plan's help desk. Moreover, there are new response fields that indicate specific phone numbers that may need to be called and what type of phone # is represented. For example, if the pharmacy needs to call the prior authorization line, then that phone# would be displayed and the pharmacy would know that they are calling the PA hotline.These fields are a huge time saving mechanism for all pharmacies, and especially in LTC, where time is of the essence. In our environment, the LTC facilities are penalized if medications are not on hand and patients miss scheduled doses. Our pharmacies have set delivery routes and schedules. If we cannot get a claim paid by the time our driver is leaving the pharmacy, then one of three things can occur: the pharmacy takes the financial responsibility, the facility takes the financial responsibility, or the medication is not dispensed and the patient may miss their schedule dose.

3. What are the anticipated barriers to implementing the new version of the pharmacy standard?
Prioritization of this change over other projects that individual companies and trading partners are working on may be a barrier. Dedicated business and IT resources for project development are key as well as adhering to the implementation timeline, and funding.

4. What if anything, would be difficult about implementing version F2 for small pharmacies? What about the new version would be difficult for small pharmacies to adjust to?
PharMerica has small pharmacy locations, but our development efforts will be spent at the corporate level and whatever changes we make will impact all our pharmacies, regardless of size. We abstain from speculating on how other small pharmacies will be impacted.

5. The HIPAA statute provides for a two year implementation window for health plans and providers after publication of a final rule. Is this time frame sufficient for your industry sector? Does the pharmacy industry want or need an overlap of the current and new standards? Thinking about the changes in health care, is there an ideal time frame for the adoption of new versions of standards, and of their implementation?
A two year timeframe was rather difficult with the last version upgrade. What I have heard from other colleagues within the industry, and what PharMerica agrees to commit to, is a three year timeline. Anything more than three years will add to the burden of not being able to solve business needs. We, the industry and PharMerica, agree that there should be an overlap. We also agree that requiring the new standard to be implemented in January or early on in a given year is problematic given that there are many other changes such as formulary and eligibility updates that occur. Given that these same types of updates also tend to occur in July, then we recommend an implementation date somewhere between March and the end of June.

6. Which industry stakeholders are impacted by implementing a new version of this pharmacy standard? Can you offer a verbal or pictorial description of the flow of the transaction, e.g. prescribers, health plans (including self-funded health plans and Flexible Spending Accounts if relevant), pharmacy benefit managers, pharmacies, pharmacy management programs, and other parties?
All or nearly all stakeholders will be impacted but the overall flow should not change. For PharMerica, our pharmacies submit a claim to the switch, the switch passes it on to the PBM, the PBM returns a response to the switch, the switch sends the response to the pharmacy and the pharmacy receives the response. If the response is a paid response, then the PBM pays the pharmacy through an 835 file or other mechanism. Nothing in this new version changes the 835 process. The changes that occur are the removal and addition of fields and the removal or addition of new field values. Yes, PBM's and switches will need to code to remove the old fields and add the new fields, but outside of that the general flow is still the same.

7. Please provide evidentiary information (qualitative or quantitative) to support the need for a recommendation to adopt version F2 at this time. If you wish to send this under separate cover because it is proprietary, that is acceptable. Should NCVHS render an affirmative recommendation to the Secretary, cost benefit data will be necessary for the regulatory process to move forward by HHS in accordance with requirements of the Office of Management and Budget.
For the talking points that I am about to cover, PharMerica can provide claim counts if necessary under a separate cover.

One issue we believe can be solved with the new version is related to the filling of controlled substances. Long Term Care pharmacies often receive rejected claims from PBM's that should be paid because LTC is allowed exceptions from normal claim processing rules. In particular, LTC is allowed to fill a CII for up to 60 days from the date written, whereas retail claims are only allowed 30. Additionally, LTC is allowed to fill in increments that are less than the amount prescribed without having to obtain a new order for each incremental dispense. For example, a physician can write an order for Oxycontin 5mg tablets to be taken twice daily. The physician can write a quantity of 60 tablets which would be good for a 30 days supply. In a retail setting, if the patient only wants a 7 days supply, then they lose the remaining 21 days and will need to seek a new hard copy prescription from their physician if they decide they need the remainder. In Long Term Care, the patient's medications are usually stocked in med-carts with limited space, and facilities may request that only 7 day supplies are sent. After the initial 7 days are consumed, LTC pharmacies are allowed to fill from the same initial order without having to obtain a new hardcopy. So in this example the 60 tablets could be filled in 7 day increments 4 times, with an additional 2 day supply that could be filled under the same order. This is known as partial filling and has been an issue for LTC pharmacies since at least 2012. NCPDP had previously requested a change to the version D0 standard to allow for the "Quantity Prescribed" field that could be leveraged to solve this business case, but we are still awaiting an NPRM. Hospice patients are also allowed the same exception in filling controlled drugs and there are changes under the CARA bill that will allow retail pharmacies to fill in the same manner. New fields for LTC partial fills and other non-LTC partial fills related to CARA legislation will provide the ability to reduce the volume of rejections that pharmacies receive and respond to, which will prevent patients from being left to pay out of pocket, which in turn reduces safety concerns where DUR information is not available because the PBM does not have paid claim information on file.

Another issue we believe will be solved with the newer version is related to compound claims. 3rd Party entities often require additional information to determine whether or not to pay a compound claim and at what rate to pay. In version D0, many payers are requiring the use of one specific field to determine reimbursement, while version F2 leverages several new fields. This is again an area of better communication between the pharmacy and PBM and also attests to the safety of the compound as the new fields can identify negative and positive pressure, sterile vs. non-sterile environments, and levels of complexity.

As mentioned earlier, the Adjudicated Program Type field that is available in version F2 is extremely beneficial to LTC. Having this information better equips us to know if any payer is a government entity. With the introduction and expansion of Managed Medicaid plans and the absence of requiring that these plans have a unique BIN, PCN, and Group ID, it has been an especially difficult and manual process to keep track of each plan's information. We've had to research this info state by state on each Medicaid entity's website. The initial effort took over a year and we are still finding out today that there are plans we missed.

As with all other claims, LTC pharmacies rely on the LTC facility to provide accurate billing information for the patient. Although we have trusted relationships with our facilities, they do not always know either and we may not have accurate information. Version F2 of the Telecommunication standard also introduces new fields to the Eligibility (E1) Response. These new fields will allow LTC and other pharmacies to have visibility into information that is not readily available in version D0. Specifically, there are new fields that identify effective and termination dates for End Stage Renal Disease and

Hospice. Many times pharmacies do not know if a patient has been diagnosed with ESRD or if a patient has elected a hospice benefit. Having this information will allow pharmacies to bill the correct Medicare entity from the start rather than rely on PBM reject edits.

Lastly, there are new response fields available in version F2 that will help clarify Benefit Maximums and Plan Limitations. These informational fields will provide a better flow of communication from the PBM to the pharmacy and then to the patient, (or in the case of LTC, to the facility.) These new fields can be leveraged to identify a minimum or maximum age allowed, dollar amount, days supply, quantity, or number of fills. These fields are beneficial not solely LTC, but to all pharmacy types.

8. What are the costs involved in implementing a new version of a standard, and by whom and to whom are they paid? For example, hardware system and software upgrades, vendor fees, real time or batch transaction fees, processing fees, clearinghouse or PBM charges, etc. Do these costs place burdens on any individual stakeholder group?
There are development costs that need to be negotiated between the pharmacy and its software vendor and/or the pharmacy switch. There are existing processing fees today between trading partners that may or may not increase with a new version of the standard. This again would need to be negotiated between the pharmacy and its trading partners. We do not believe the costs place burden on any individual stakeholder group.

9. What are the patient service and care impacts to implementing version F2? For example, are there patient service and care impacts version F2 will solve/resolve, or are there potential service issues the new standard could create?
The patient service benefits have already been stated. Version F2 of the standard allows much more information to be communicated between the pharmacy and PBM and thus to the patient. The flow of this information greatly reduces medication availability issues that may occur today. The new version also adds fields that enhance safety edits for the PBM and patient. Nothing that PharMerica has identified in the new version would cause service issues, except if trading partners are not ready to accept the new version by the defined regulatory date.

10. What are the consequences to industry if NCVHS does not recommend adoption of Version F2 to the Secretary?
Without adoption of the new version, the industry continues to have unsolved business needs. We're also at a disadvantage to be able to respond to ANSI requirements to expand what has been known as the Bank Identification Number and is now known as an Issuer Identification Number from 6 to 8 digits. Additionally, we are not able to comply with FDA requirements for Unique Device Identifiers as the UDI is up to 40 characters in length and our current standard only allows for a product length of 11.

11. Is there any opposition to the upgrade to Version F2?
Not that we are aware of. NCPDP is a consensus building organization and from the quarterly meetings that I've attended there seems to be consensus among pharmacies, PBM's, vendors, and other generally interested parties.

12. What is the burden reduction to your stakeholder group for use of Version F2?
I think this has been answered in speaking about the benefits. There is more information available that can be communicated from either the pharmacy to the PBM or vice versa. We believe the more

information that is available to each party; the easier it will be to communicate needs to our patients, facilities, prescribers, and other covered entities. We believe the introduction of much of this new information will speed the process of filling a prescription, having to call for an override, or to seek prior authorization, and will provider better patient care. We also believe that interoperability and patient safety are enhanced.

1. Is there anything else you deem relevant, important and appropriate to inform the committee and HHS about adoption and implementation for each of these standards?
No

2. What testing has been done of the standards to demonstrate that they are ready for use?
To my knowledge, no testing has occurred.