

Publishing and Maintaining Externally Developed Implementation Guides

Background

X12 publishes implementation guides that define consistent use of one or more of X12's transactions for a specific business purpose. Other consensus-based organizations that represent the interests of specific industries and sub-industries are interested in the availability of additional implementation guides that carry the weight and authority of X12's moniker and support their specific business activities.

Although using X12's primary development process as outlined in the *ASC Standards Development Manual (ASC02)* remains the preferred method for developing these additional implementation guides, in some cases circumstances prevent or impede the use of that development method. Examples of these extenuating circumstances include X12 not having member representatives who are subject matter experts on specific business activities and X12 groups having a workload that does not support timely development of the additional implementation guide. In each of these situations, it is advantageous to have an established consensus-based process that allows for X12 review of implementation guides developed outside of the Accredited Standards Committee.

Proof of Concept

The activity selected as the proof-of-concept for this pilot is a request from NCPDP, another ANSI-accredited standards developer. X12 and NCPDP have a long history of successful, cooperative, collaborative activities.

NCPDP is interested in the publication of an implementation guide standardizing the use of X12's 846 transaction for the exchange of specific inventory information between manufacturers and specialty pharmacies. NCPDP needs the implementation guide published quickly, preferably in the first quarter of 2020.

The 846 transaction is maintained by X12M. X12's technical report library does not currently include any implementation guides related to the use of the 846 transaction set.

Within X12, products that support the health care industry are the responsibility of X12N. X12N does not have a task group or work group with specific responsibilities or expertise related to specialty pharmacies.

Pilot Evaluation

The pilot shall be deemed a success if the pilot result in publication of the identified implementation guide within 6 months of approval of the pilot. At Steering's discretion, the pilot may be deemed a success if publication occurs within 9 months of approval of the pilot. Upon a successful pilot, the policies, processes, and concepts described herein will be converted into a long-term subcommittee policy/procedure.

Pilot Policies

X12 establishes the following policies as governance for the pilot.

- The pilot is established as a committee-level pilot.
- The draft implementation guide will be developed using X12's technical report development tools.
- The final implementation guide will be produced using X12's standard publication processes, tools, style, and format.
- Approval to publish will be based on the pilot process described herein or in a subsequent revision.
- The pilot process will be patterned off the approved *Crosswalk Pilot (PIL01)* and the *ASC Standards Development Manual (ASC02)* where possible.
- Progress shall be monitored by the PRB chair, with staff assistance as requested.
- Since there is a technical component involved, an X12J technical review shall be required.
- ASC subcommittees shall not define additional procedural steps under this pilot. All procedural steps are defined herein or in a subsequent revision.
- X12M and X12N shall both establish majority approval before the proposed work is presented for an X12J technical review.
- The X12M and X12N subcommittees shall simultaneously complete their review and ballot process as described below. Any comments on the proposed work shall be presented during balloting, not as part of the review period.
 - If the draft implementation guide is presented for subcommittee review and ballot more than 45 calendar days or fewer than 30 calendar days before the next Standing meeting commences, the subcommittee chair shall authorize a 30-day electronic constituent ballot which shall also serve as the subcommittee's review period.

- Otherwise, the review period shall occur prior to the commencement of the Standing meeting and the subcommittee chair shall conduct an X12N constituent meeting ballot during the Standing meeting.
- The subcommittee reviews shall be conducted via X12's online reviewer. As noted above, any comments on the proposed work shall be presented during balloting, not as part of the review period.
- Since the implementation guide is based on an X12M maintained transaction, X12M shall be assigned primary responsibility, shall shepherd the maintenance request through the pilot process, and shall conduct an X12M constituent ballot as described above seeking approval to move the implementation guide forward for publication.
- Since the implementation guide is related to the health care industry, X12N shall be assigned review responsibility. X12N does not have a task group or work group with specific responsibilities or expertise related to specialty pharmacies so all review and balloting shall be conducted at the subcommittee level. X12N shall conduct an X12N constituent ballot as described above seeking approval to move the implementation guide forward for publication.

Pilot Process

The process laid out below assumes best-case results. If there are setbacks in the best-case plan, the ASC chair, PRB chair, X12M chair, and X12N chair shall determine the appropriate procedural fallback based on the procedure defined herein. If the chairs cannot agree on an appropriate procedural fallback, Steering will review the situation, amend this pilot plan to cover the situation, and approve a new version of this pilot plan.

The committee establishes the following process for the pilot. Unless otherwise specified, the steps occur sequentially in the order shown below.

1. The X12M chair submits a maintenance request for the proposed implementation guide in alignment with ASC02 Section 2.2. The MR shall follow the usual path through PRB and X12J.
2. Subcommittee Responsibilities – these steps shall occur concurrently:
 - a. X12M shall review the implementation guide and conduct an X12M constituent ballot seeking approval to move the implementation guide forward for technical review.

- b. X12N shall review the implementation guide and conduct an X12N constituent ballot seeking approval to move the implementation guide forward for technical review.
 - c. The review period shall be announced to any X12 member representative who attended at least one X12M or X12N full subcommittee session at one of the last three Standing meetings.
3. Balloting
- a. If a meeting ballot is conducted, the subcommittee chairs shall be responsible for the ballot logistics. Upon request, staff will provide written comment forms to facilitate collection of meeting ballot comments.
 - b. If an electronic ballot is conducted, staff prepares an electronic constituent ballot for each subcommittee and notifies eligible subcommittee constituents. The eligible subcommittee constituents are determined according to each subcommittee’s usual criteria.
 - c. Ballot comment responses
 - i. The X12M project delegate shall work with NCPDP to create a response to each ballot comment that is related to the technical or business content within the implementation guide.
 - ii. The ASC chair shall create a response to ballot comments related to other matters.
 - iii. Staff will distribute the responses to the commenters.
4. If approval to move the implementation guide forward for technical review is achieved within X12M **and** X12N, the X12M project delegate will request X12J technical review.
5. Technical and Due Process Review
- a. X12J shall conduct a technical review per their normal procedures as defined in ASC02.
 - b. Following majority approval from X12J, PRB shall evaluate to ensure due process was achieved, based on this pilot process.
6. Following PRB approval to publish,
- a. The X12M project delegate notifies NCPDP of the approval.
 - b. Staff publishes the implementation guide.

Document History

Approved	Description
12/05/2019	V1: Pilot Approved by Steering