NCPDP STANDING OPERATING PROCEDURES

This document contains the procedures related to the structure and standards setting process of the National Council for Prescription Drug Programs.

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I.   INTRODUCTION

The National Council for Prescription Drug Programs, Inc. (NCPDP) is located in Maricopa County in the state of Arizona. Formed in 1976, NCPDP is a not-for-profit organization dedicated to the development and dissemination of voluntary consensus standards. NCPDP's standards documents are used for information transfer processes associated with the pharmacy services sector of the healthcare industry. NCPDP's membership is broad based within this segment of the healthcare industry.

Membership representation exists as defined in the NCPDP *Bylaws* and is divided among three classes of membership.

Refer to the NCPDP *Bylaws* for more information.

A.   Vision, Purpose and Goals

The vision of the Council is to lead the industry in healthcare standards and solutions for the common good. The purpose of the Council is to standardize the exchange of healthcare information to improve outcomes. This is accomplished through the exploration and application of appropriate knowledge transfer technologies, within the diverse group of healthcare providers, payers and related information processors that are participants in this segment of the healthcare industry.

The Council achieves this purpose by establishing and maintaining a forum that facilitates the development, publication, implementation, maintenance and control of standards for information processing. It also promotes and monitors the use of these standards among its diverse membership and other interested or materially affected parties. The Council is committed to working cooperatively with all groups dedicated to improving the quality and efficiency of healthcare delivery, financing and administration.

Through open communication, active pursuit of balanced representation and continuous consensus building, all of which are conducted to ensure due process, the Council operates standardization Work Groups which develop standards documents; and maintains records of all Work Group explorations and considerations, according to applicable sections of the NCPDP *Bylaws* and the *Standing Operating Procedures.* The information content of the Council's standards documents shall not intentionally unfairly favor the proprietary characteristics, interests, specific products or systems of one organization or company over another.

The Council shall copyright and own all standards documents created by its standardization Work Groups. The documents will be actively promoted for use by any interested party, and be provided by the Council to any party upon payment of fees established by the Board. The Council's copyrights shall be established to assure control of the accuracy of the published standards documents, although they shall not prevent the Council from granting permission for accurate reproduction and further dissemination of those materials, in part or in full, in order to promote the use of those standards.

NCPDP shall operate as a not-for-profit association with funding from sources such as but not limited to membership dues, meeting registration fees, delivery of membership services, provider services, joint ventures, sponsorship opportunities, publication sales fees and standards subscription fees. All fees are approved by the Board.

B.   Membership

Membership shall be open to any individual, sole proprietorship, partnership, corporation, firm or other organization which is involved with any aspect of the pharmacy services sector of the healthcare industry. Membership shall be open to all persons who are directly, indirectly, or materially affected by the production of the Council's standards documents, including members of other healthcare professions, trade associations, standards development organizations or government entities. Anyone may make application for such membership by filing an application with the Council accompanied by payment of dues.

Members shall be classified in accordance with the NCPDP *Bylaws*.

Members of the Board of Trustees, Work Group and Standardization Co-Chairs and Committee members are required to sign a confidentiality and non-disclosure agreement.

II.   ORGANIZATIONAL STRUCTURE

The working organizational structure is graphically depicted in the following organizational chart. Various reporting, management responsibility and support relationships are shown. In addition, the leadership selection control points are depicted. Every level of the Council's leadership and working committees is intended to possess a balance of the three membership classification interests that help ensure true consensus in development and the rigorous application of due process in all standardization efforts.

Multiple leaders are appointed to bring various perspectives to the leadership of each individual organizational unit. Leaders seek a balance of interests in determining whether consensus on a particular issue exists during Task Group and Work Group discussions.

Membership
(Producer & Provider, Payer & Processor, Vendor & General Interest)

Elects

Volunteers

Chair

Executive Committee

Elects

Board of Trustees

Appoints

Appoints

Committee Co-Chairs

Standardization Co-Chairs

President

Committees

Technical Work Group Co-Chairs

Maintenance and Control Co-Chairs

Council Staff

SubCommittees

Elects

Maintenance and Control Work Group and Technical Work Groups

Appoints

Task Groups

Non Members may participate in some subcommittees (limitations)

Non Members may attend Work Groups (limitations)

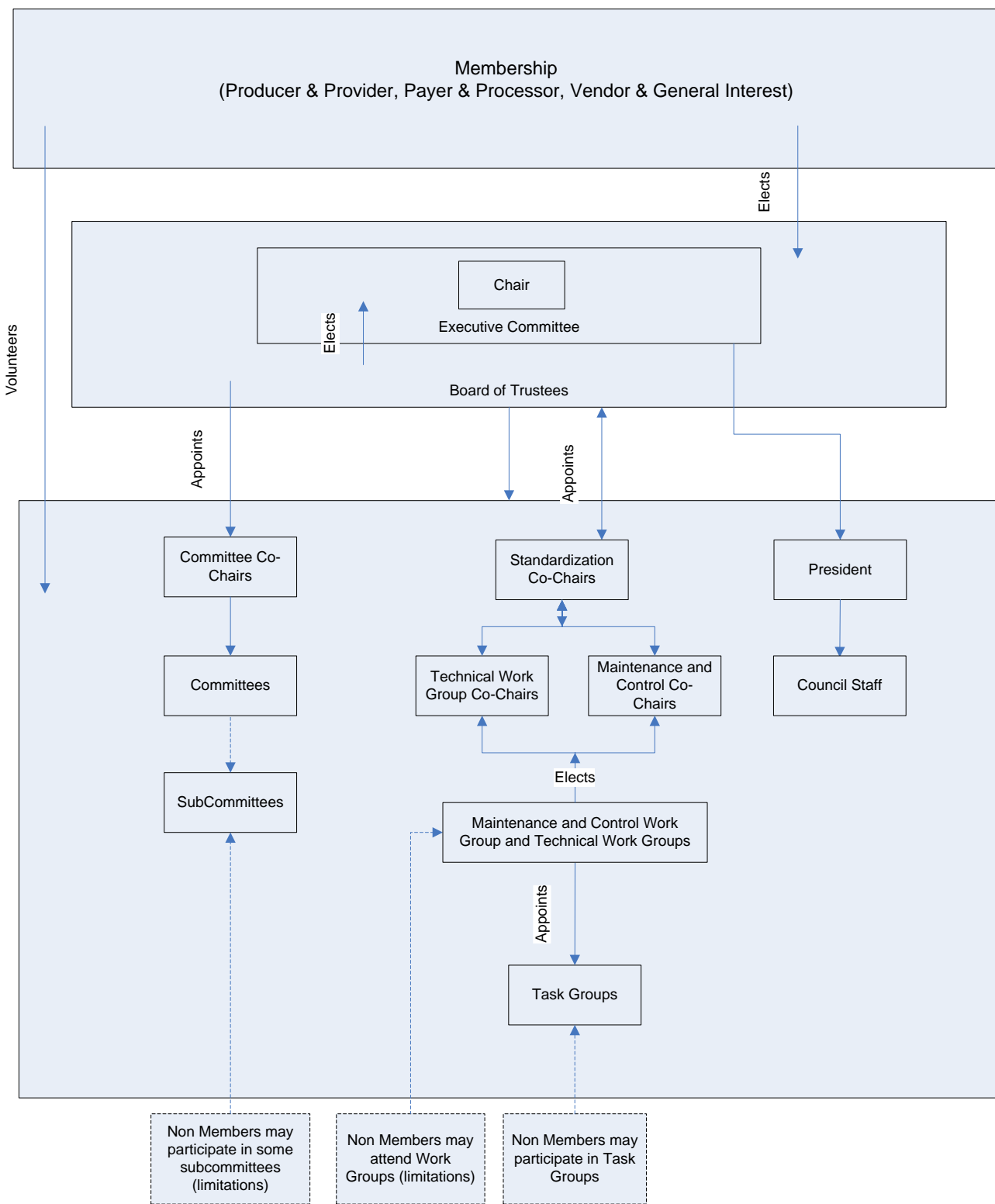Non Members may participate in Task Groups

Figure 1: Organizational Structure

NCPDP's working organizational structure consists of:

A. The Membership

The members elect a Board and provide the volunteer work or the "engine" that drives all Council standardization efforts. Members volunteer time and company resources to participate in the standardization development efforts and also provide the leadership of those efforts by serving as Work Group Co-Chairs, Task Group Leaders, Standardization Co-Chairs, Committee Chairs, and as Trustees.

B. The Board of Trustees

The Board of Trustees (the Board) oversees all Council activities. The Board has final authority regarding the procedural adherence in all Council industry standardization development activities and the application of those standards for candidacy as American National Standards. The Board sets the strategic direction of the organization and is charged with the fiduciary responsibilities associated with operating the Council. The Board annually elects a Chair, Vice Chair and other officers it requires to conduct its business. Board officers must be members of the Board. The Board also appoints standing committees and may appoint ad-hoc committees.

The Board retains final authority on whether referred actions or referred items are appropriately prepared for Council membership consideration. All actions related to the Council's standards must be presented to the membership via a data maintenance ballot. The Board shall have final authority on all industry standard development procedures, appeals, and the conduct of process documentation record retention.

C. The Executive Committee

The Executive Committee as defined in the NCPDP Bylaws has the authority to act between scheduled board meetings.

D. The President

The President is the Council's Chief Executive Officer and has complete management responsibility for all paid staff. The President is responsible for the day-to-day operations of the Council and the security and retention of Council's records and other assets. The President provides continuity, support and a paid staff management perspective to the Council's elected volunteer leadership who serve limited terms in office. The President reports to the Board through the Chair of the Board and the Executive Committee.

E. The Staff

The Staff are employees of the Council and ultimately report to the President. The paid staff provides logistical and administrative support for the President, the volunteer leaders, and the volunteer Work Group and Committee members whose efforts drive the Council's standardization activities. The paid staff is primarily responsible for conducting the daily administrative operations related to the provision of the Council's products and services to the membership. Staff responsibilities include, but are not limited to, the following:

- Communications - developing all forms of public communications distributed from the Council.

- Finance/Human Resources - managing the Council's financial accounts, budget, and all human resource functions.

- Information Systems - managing and maintaining internal system operations, and overseeing the development and maintenance of the NCPDP web site.

- Meeting Planning - planning and preparing all meetings and events facilitated by the Council.

- Membership - managing and maintaining all information and services related to membership.

- Database Services - managing and maintaining all products and services for NCPDP subscription databases.

- Standards Development - ensuring the proper procedures are followed in NCPDP's standards development efforts, facilitating the creation of NCPDP documents, and providing liaison support to NCPDP Work Groups, other standards development organizations, industry working groups, and government agencies.

- Sales and Marketing - new business development, creating/enhancing products and developing/ implementing sales and marketing programs.

F. The Standardization Committee

The Standardization Committee is responsible for the Council's standards documents development and maintenance efforts. Composition of the Standardization Committee is defined in Section VIII.C.5. of the NCPDP Bylaws. The Standardization Committee shall seek balanced representation of membership categories in its members. Members of the Standardization Committee shall be referred to as "Standardization Co-Chairs".

The members of the Standardization Committee shall be appointed by a majority vote of the Board at their first regularly scheduled meeting of the calendar year. The Committee has line management responsibility for all Technical and Maintenance and Control Work Group ("Work Groups") activities. The Standardization Committee reports to the Board and makes recommendations to the Board on the:

- Scopes of work, maintenance, name or other operationally related requests
- Work Group initiated documents
- Transmission of Work Group documents as candidates to the American National Standards Institute
- Overall direction of standardization efforts, relationships and interaction with other stakeholders and interested parties
- Enhancement of staff support or changes in procedures which would improve volunteer consensus standards development efficiencies and quality

G. Work Group Co-Chairs

No less than two and no more than three Chairs of each Work Group shall be elected by the members following the annual nominations and election administered by the Standardization Committee. Following public notice of an upcoming election of Work Group leadership, any member may submit to the Standardization Committee Liaison his or her name, or the name of another member for nomination. The Standardization Committee shall appoint interim or acting Work Group Co-Chairs as required to fill vacancies and at the initial formation of a Work Group.

Responsibilities of the Co-Chairs include, but are not limited to:

- Attendance at all Joint Technical Work Group meetings, unless an absence has been excused.

- Development of agendas

- Facilitation of all scheduled meetings, exercising leadership, and supporting the Work Group's charge

- Formation of Task Groups and appointment of Task Group Leaders to investigate specific subjects, conduct detailed development work efforts or develop recommendations for full Work Group consideration

- Movement of Work Group members toward participation, decision-making and consensus.

- Oversight of accurate meeting minutes, including attendance roster.

H. The Work Groups

The formation or consolidation of a Technical or Maintenance and Control Work Group, and if appropriate, later disbandment, requires the approval of the NCPDP Board that acts on recommendations provided by the Standardization Co-Chairs. The Council's membership is notified of any new Work Groups being created, any proposed disbandment and of proposed changes in the scope or direction of Work Group activities. Work Groups are given a Work Group number designation in addition to the name, for reference and to simplify the document retention and control functions of the Council. For example, "WG9" is the Government Programs Work Group.

The Work Group's preliminary scope of work or charter is established by the Standardization Co-Chairs with the approval of the Board of Trustees. After its formation and initial consideration of scope and domain issues, the Work Group members shall vote to define a proposed scope of work and request the Standardization Committee and Board approval to authorize this new scope. Any subsequent changes in name, scope, duties, authorities or responsibilities of the Work Groups shall also require Standardization Committee and Board approval.

The Work Groups contain the vast majority of volunteer energy and dedication required to create voluntary standards that are acceptable consensus compromises among the diverse and often competing perspectives of the NCPDP membership. All standards document development, maintenance or modification/withdrawal efforts originate in the Work Groups, but are resolved through membership data maintenance ballots and Standardization Committee recommendations for Board of Trustee certification of the data maintenance ballot results. Work Groups adjudicate data maintenance ballot comments, develop responses and document their considerations of these written member comments on data maintenance ballot issues through official meeting minutes and ballot comment resolution documentation. The Work Groups may also produce and approve guidance and reference documents.

NCPDP Work Groups' scope of work and charge shall include, but not be limited to, the following general responsibilities as further described in these *Standing Operating Procedures* and the *Bylaws*:

- Each Work Group is responsible for the development, ongoing maintenance and any recommendations for withdrawal, of one or more of the Council's standards documents, when applicable.

- The Work Groups are also responsible for the development of draft and final documents, addressing any ballot comments, requests for clarification, assistance, unsolicited views, and objections voiced by any individual or organization, which may have been received as a result of the use, notice or distribution of any proposed or current NCPDP standard or other document and other investigative, review or advisory functions as determined by the Board or the Standardization Co-Chairs.

- All Work Group proceedings and considerations shall comply with the provisions set forth in these *Standing Operating Procedures* and the *Bylaws* that are associated with all official actions of development, maintenance, withdrawal and oversight of the Council's standards documents.

1. *The Maintenance and Control Work Group*

The Maintenance and Control Work Group reports to the Standardization Committee. Co-Chairs are responsible, with the support of the staff liaison, for the maintenance of complete and accurate documentation records, including all due process, considerations and adjudication of comments received. Maintenance and Control Work Group provides a forum for updates of Work Group activities and resolution of inter-Work Group issues. Maintenance and Control Work Group may establish task groups to support their work items.

The Maintenance and Control Work Group shall simultaneously, and in a coordinated manner as directed by the Standardization Co-Chairs, consider issues under deliberation among Work Groups and Task Groups. The Maintenance and Control Work Group shall provide oversight advice, support, education and advisory opinions on issues arising from Work Group and Task Group efforts. The Standardization Co-Chairs will direct and assist in the coordinated consideration of issues by Technical Work Groups and the Maintenance and Control Work Group. The Standardization Co-Chairs may refer issues which Technical Work Groups cannot resolve to the Maintenance and Control Work Group for deliberation and recommendation on resolution.

Data Dictionary Issues: Maintenance and Control Work Group determines the appropriateness of Data Element Request Forms being considered by various Technical Work Groups. Maintenance and Control Work Group reviews field and code definitions and oversees Technical Work Group requests which affect the Council's Data Dictionary. It prevents duplication and/or conflict between existing data elements. Field and code identifiers are assigned by Council staff.

Technical Assessment Issues: Maintenance and Control Work Group reviews all actions taken by Technical Work Groups in a quality assurance oversight role. Technical assessment ensures that any changes or development actions of these groups do not adversely affect the architecture and other technical design considerations of the Council's standards. Maintenance and Control Work Group Co-Chairs will review the Technical Work Groups' actions between each scheduled Technical Work Group meeting to ensure that Technical Work Groups have not inadvertently compromised function or standards design intentions.

Application Assessment Issues: Maintenance and Control Work Group reviews the actions of Technical Work Groups from a business case perspective. Maintenance and Control Work Group will evaluate whether the Technical Work Group's handling of dissenting opinions, comments received and decisions made regarding a standard's function is justified and appropriate. Maintenance and Control Work Group will advise the Standardization Co-Chairs of issues of development procedure and due process compliance, as well as any ethical and legal controversies that may develop in Technical Work Group proceedings and other areas where Technical Work Groups may be unable to reach consensus due to non-technical considerations.

Maintenance and Control Work Group may hold hearings or other open forums during regularly scheduled Joint Technical Work Group meetings on issues under consideration in order to resolve or further research an issue. They may create written rulings and recommendations for Standardization Co-Chair and Board of Trustee consideration. In their quality assurance oversight role, they may suggest that issues or actions that they determine are inaccurate or inappropriate be referred back to the originating Technical Work Group. The Standardization Co-Chairs shall make final determinations on such suggestions and coordinate referral and reconsideration by source groups.

I. Task Group Leaders

The Task Group's Leader will be appointed by the Co-Chairs of the overseeing Work Group. A Task Group Leader must be a member of NCPDP. Each Task Group Leader must strive to ensure the balance of interest among the Task Group members, and always strive to achieve consensus through open consideration and due process. Open consideration permits all interested or materially affected parties to provide input to considerations. Task Group Leaders should seek opinions from members and non-members that may be affected if their deliberations and actions proceed toward membership and general public consideration.

J. Task Groups

Task Groups shall be formed as needed, to address specific issues or complete specific functions for the Work Group. The Task Group is formed with approval of the Work Group and is made up of interested parties. A Task Group Leader must be identified before the Work Group can approve its formation. The Task Groups typically conduct their work efforts between official Joint Technical Work Group meetings.

The Task Group is responsible for the research, development and consideration of proposed positions or for the documentation of individual issues for one or more Council standards documents as assigned by a Work Group. The results of their efforts and/or their recommendations must be presented to the Work Group for their consideration.

Task Groups are ad-hoc in nature, and should be disbanded once the project or task they were charged to address is complete, as determined by the Co-Chairs of the overseeing Work Group and/or the Standardization Co-Chairs. If there is no activity reported by the Task Group over the course of two consecutive work group meetings, the Co-Chairs of the overseeing Work Group should consider if the Task Group should be disbanded or placed on hiatus. "Hiatus" implies there are external factors or actions which prevent a Task Group's work moving forward. The specific factors which will remove the Task Group from hiatus must be documented in the Task Group Recap to the Work Group. Task Groups on hiatus should be reevaluated periodically to determine if there are changes to the external factors which will either (a) justify removing the hiatus of the Task Group, or (b) disbanding the Task Group if the project or task is no longer relevant.

III.   MEETINGS
A. General - All Meetings

All meetings of the Council shall proceed according to the specifications of the NCPDP *Bylaws* and include reading of the Council's Antitrust Policy. Task Group meetings may waive the reading of the Antitrust Policy. All meetings, with the exception of the Board and standing committee meetings may be open to attendance by any member or materially affected parties.

Meetings are governed by the latest edition of *Robert's Rules of Order* as long as they are not in conflict with the NCPDP *Bylaws*.

The general format for meetings shall be:
I.   Call to Order (Note Time)
II.   Reading of the Council's Antitrust Policy
III. The Agenda
    A.   Overview (Chair)
    B.   Call for Additions or Modifications (Chair)
    C.   Approval of the Agenda (Body)
IV.   The Minutes
    A.   Review Previous Minutes (Chair)
    B.   Call for Additions or Modifications (Chair)
    C.   Approval of the Minutes (Body)
V.   Old Business
VI.   New Business
VII. Adjournment (Note Time)

B. Joint Technical Work Group Meetings
1.   *Notice*

Joint Technical Work Group Meeting notifications must occur at least 30 calendar days prior to the scheduled meeting and include the date, location and time of meeting. Notice will be sent through one or more methods to the membership, the cooperating Standards Development Organizations and other potentially interested parties. All meeting notifications are filed with the Council.

Joint Technical Work Group meetings are open to all Council members and other non-members interested in, or otherwise materially affected by, Council activities. Non-members are not permitted to vote on official

Council actions although their views shall be considered and documented in the same manner as a Council member's views. All participants will be encouraged to become a member of NCPDP.

Members and non-members who plan on attending Joint Technical Work Group sessions may be required to extend advanced registration notice of their intent to attend to the Council. The Board of Trustees shall review Joint Technical Work Group session operational costs and may impose a registration fee for members and/or non-members to cover Council costs.

2.   *Quorum*

Ten percent of the Council's members registered shall constitute a quorum for a valid Joint Technical Work Group to be convened.

3.   *Documentation*

Joint Technical Work Group meetings shall have the following documentation created and filed with the Council in a timely manner.

Agenda
An agenda using the general format above indicates the time, place and type of meeting, in addition to subjects to be covered. Agendas or meeting notices should reference relevant subject documents or other materials to be considered at the meeting. This agenda must be filed at the Council according to any minimum notice requirements which may affect a particular meeting.

Attendance List
Attendance at Work Group meetings is accounted for by the electronic scanning of badges in each of the Work Group meetings and is available at the Council office.

Minutes
Complete minutes of meetings must be filed at the Council as soon as possible after the meeting, but not later than 30 business days after the meeting.

4.   *Voting*

Work Group members may vote on any issue under consideration during the meeting. Voting should be reserved to verify consensus on issues and to close items under consideration. Divided votes should be considered an indication of the opportunity for further discussion that may build greater consensus. Each Council member is entitled to vote at Work Group sessions although Co-Chairs shall examine those voting to ensure that reasonable balance of representation is present and to confirm that no non-members are voting. Each Work Group Co-Chair shall strive to ensure balance of representation among the Work Group members and always strive to achieve consensus through open consideration and due process. Balance of interests may mean that no single classification segment of the membership (Producer & Provider, Processor & Payer or Vendor & General Interest) represents more than half of the voters who are voting on a particular matter under consideration. Co-Chairs shall strive to limit the ability of a block of voters in a single classification, which represents more than half of the votes being cast, from overwhelming the interests of either one of the remaining classifications with dissenting opinion. Due process requires that any materially affected party may participate in the deliberations of a Work Group and that dissenting votes and opinions are carefully considered and addressed by the approving side of an issue. Minutes of deliberations shall include a summary of all such dissenting opinions noted and the results of their consideration.

Open consideration means that Work Group Co-Chairs permit all interested or materially affected parties to provide input during deliberations. Work Group Co-Chairs should seek opinions from members and non-members that may be affected by their deliberations as their development and maintenance actions proceed toward membership and data maintenance ballot consideration.

Consensus does not mean that a formal vote has occurred and that a majority side has prevailed. Voting should be a means of confirming near unanimity on an issue. Consensus development and consideration always seeks compromise of positions that leads to near unanimity on decisions. Once consensus has been reached by the Work Group, their recommendations may be presented to the Standardization Co-Chairs, Board and ultimately the Council membership for approval. The process of smaller organizational unit (i.e., Task Group then Work Group) consideration of positions that are passed to successively higher management levels and larger organizational units which must also reach consensus, which helps ensure successful consensus consideration by the largest organization unit, the membership.

If the Work Group actions related to an issue's development is truly consensus driven, successful movement of the issue through the higher management and larger organizational units is more likely to occur.

C. Interim Meetings

The Board or the Work Group Co-Chairs may request other meetings to conduct development or other deliberations related to the Council's standards. These meetings, called by the Standardization Co-Chairs, may occur between official Joint Technical Work Group meetings. Notice of an interim meeting shall be provided to the membership and general public not less than 30 calendar days prior to the date of the meeting and shall include the subject or subjects to be considered. Ten percent of the Council's members registered for the interim meeting shall constitute a quorum for a valid interim Joint Technical Work Group to be convened. As with all meetings of the Council, an agenda for each meeting shall be created and an attendance list and minutes of proceedings shall be kept for all Work Groups.

D. Special Meetings of the Membership

Special meetings of the membership shall be called by the Chair of the Board upon the written request of 20% of the membership. Notice of any special meeting of the membership shall be sent to each member not less than 30 days prior to the date of the meeting and shall include the subject or subjects to be considered. No subject(s) other than those specified in the notice of the special meeting shall be brought before the members for a vote.

IV.   STANDARDS DEVELOPMENT PROCESS

NCPDP develops and maintains several types of documents: American National Standards (ANS), NCPDP Standards, and NCPDP Guidance documents. At the initiation of a project to develop or revise an ANS (excluding an ANS maintained under continuous maintenance), notification shall be transmitted to American National Standards Institute (ANSI) using their Project Initiation Notification System (PINS) form for their announcement in *Standards Action*. *NCPDP will address any assertions of conflict or duplication in accordance with clauses 2.5.1.2 and 2.5.1.3 of the current edition of the ANSI Essential Requirements.*

A. Submission of a New Project Development Form

A project is a business need that the submitter believes the NCPDP membership should address. The business need may be broad (industry wide) or narrow (entity or segment) in scope. A New Project Development Form is submitted according to the same timeline as Data Element Request Forms (DERF). A New Project Development Form is reviewed by staff for completeness prior to the Joint Technical Work Group meeting.

The New Project Development Form is reviewed by the Maintenance and Control (MC) Work Group who shall recommend either approving as submitted, approving with modifications or rejecting the proposal. If approval is recommended, MC then recommends which work group should be assigned the project.

The recommendations from the Maintenance and Control Work Group are reviewed by the Standardization Committee. The Standardization Committee shall review the New Project Development Form request and recommendations from the Maintenance and Control Work Group. The Standardization Committee shall

submit recommendations to the Board that may follow the recommendations made by the Maintenance and Control Work Group or offer different recommendations that consist of approving the request as submitted, approving with modifications or rejecting the proposal.

The Board reviews the Standardization Committee's recommendation and notifies the Standardization Committee of their decision, which may include acceptance of the Standardization Committee's recommendations or approving the request as submitted, approving with modifications or rejecting the project.

A project is considered accepted by the NCPDP members once the Maintenance and Control Work Group, the Standardization Committee, and the Board of Trustees have reviewed the project and it is approved by the Board.

Approval of the project means that an existing or new Work Group will put the project on their agenda for discussion at their next scheduled meeting and determine next steps.

Actions by the Work Group may include:

- The development of white papers.
- Submission of Data Element Request Form (DERF) for changes to existing standards and implementation guides.
- Creation of a Task Group.
- Creation of a new standard or implementation guide.

At each step of the review process NCPDP staff will notify the submitter of the project status, with any accompanying information.

B. Submission of a Data Element Request Form

Each Work Group is responsible for the development, ongoing maintenance and any recommendations for withdrawal, of one or more of the Council's standards documents, where applicable. Any individual or group may submit a request for new standards or modifications to existing standards using the Data Element Request Form (DERF). More information on the DERF process is available at www.ncpdp.org.

A DERF is submitted to the Council with applicable proposed documentation such as a standard implementation guide, additions, deletions, and/or revisions to the Data Dictionary and External Code List, and a modification log. The DERF and documentation is reviewed by staff for completeness prior to the Joint Technical Work Group meeting. The DERF is submitted to the Standardization and Maintenance and Control Co-Chairs for Work Group assignment. The DERF is posted to the NCPDP website prior to the Joint Technical Work Group meeting. Submitters are encouraged to attend the Joint Technical Work Group meeting to discuss the request.

C. Work Group Review of DERF

The assigned Work Group(s) reviews and deliberates on the DERF and supporting documentation. Actions by the Work Group(s) to the DERF may include approval as submitted, approval with modifications, no action pending further information, or denial with cause. The Work Group(s) then sends the DERF to Maintenance and Control for final resolution.

D. Maintenance and Control Work Group Review of DERF

A DERF may be presented to Maintenance and Control Work Group directly or via the Technical Work Group(s). Maintenance and Control Work Group follows the same process as the Technical Work Groups when reviewing DERF requests. Maintenance and Control also reviews the outcome of the Technical Work Group(s) deliberations and facilitates consensus when needed. Maintenance and Control Work Group submits the final DERF resolution to the Standardization Co-Chairs.

E. Standardization Co-Chairs Review of DERF

Once consensus has been reached at the Work Group level on a proposed standard, maintenance to a standard, withdrawal of a standard, etc., and the necessary oversight review by the Maintenance and Control Work Group has occurred, the Standardization Co-Chairs will review final documents with the Council staff and make recommendations on further membership actions to the Board. The Standardization Co-Chairs ensure that the documents created, data maintenance ballots proposed, comment responses created and ballot results recommended by the Work Groups are complete, accurate and of acceptable quality in terms of content and process. They ensure that the Council staff has appropriate automated control of documents and materials proposed to move toward membership consideration under ballot or survey. The Standardization Co-Chairs ensure that all appropriate Work Group review of items has been coordinated.

V. STANDARDS DATA MAINTENANCE PROCESS

A. Forming the Consensus Group

A data maintenance ballot shall be open to NCPDP members and all persons who express an interest in commenting on ballots related to standards development activities. Prior to the first data maintenance ballot of each calendar year, NCPDP will survey the membership and general public to identify those parties willing to participate in the Consensus Group for new data maintenance ballots coming out of the Technical Work Group meetings held in that year. A new Consensus Group will be formed prior to the first data maintenance ballot of each calendar year based on the results of this survey. Before the close of the survey period, NCPDP shall send a reminder notice to the membership and general public. The Consensus Group is expected to vote on all new data maintenance ballots coming out of those Technical Work Group meetings and follow those ballots through completion. Interested parties responding to the survey shall become the Consensus Group, according to the following criteria:

1. The Consensus Group must consist of at least thirty participants.
2. NCPDP shall review the list of respondents and ensure that the Consensus Group represents a reasonable balance of interests which requires that no single membership classification constitutes a majority of the Consensus Group.

Removal from the Consensus Group
A Consensus Group member shall be removed from the Consensus Group upon request via written communication. The member will be removed from the Consensus Group for the next new data maintenance ballot coming forward. Upon removal of a Consensus Group member, the total number of individuals in the remaining Consensus Group will be adjusted accordingly and balance maintained.

B. Notice of Ballot

Notice of a data maintenance ballot shall be provided to the Consensus Group. The notice is released at the beginning of the data maintenance ballot period. Concurrent with the voting period of a data maintenance ballot, NCPDP should transmit the BSR-8 to ANSI.

C. Voting Period

The voting period for all data maintenance ballots shall provide voters with a minimum of 45 calendar days for ballot return as specified in the ballot. During the voting period of the ballot, the Consensus Group has the opportunity to submit comments via the established procedures.

The Standardization Co-Chairs shall have the option of granting an extension of the data maintenance ballot period when such an extension is warranted.

D. Voting Options

An official data maintenance ballot must provide the opportunity for the Consensus Group to vote:

1) Affirmative, with comments. (The voter may provide comments that are editorial in nature; however, comments are not required.)

2) Negative, with reasons. (Negative votes must contain a reason and be accompanied by documentation that includes specific paragraph, sections, or parts to which the negative comments pertain, specific substantive reasons for the objection and/or specific wording or actions that, if accepted, would resolve the objection and result in the vote being changed to an affirmative or abstain.)

3) Abstain. (Abstentions shall be counted as a valid ballot for the purpose of meeting consensus requirements. Abstentions do not count toward the affirmative or negative side of the equation when calculating ballot results.)

Votes must be completed and posted/returned within the time frames specified within the data maintenance ballot and explanatory materials. Ballot votes received after the official voting period will be excluded from the tallying process.

E. Vote Changes

The Council shall not change a vote on a data maintenance ballot unless instructed to do so by the voter.

F. Valid Data Maintenance Ballot

In determining the validity of a new ballot, a quorum shall be defined relative to the number of Consensus Group members. In order to be valid, 60% of the Consensus Group must return their ballots and all negative with reason votes must be adjudicated as described below by the originating Work Group.

G. Resolution of Comments

Prompt consideration shall be given to the expressed views and objections of all submitters, including those comments received through the public review process. If resolution is not achieved, each such objector will be notified in writing of the right to appeal.

Comments Not Related

At the close of the data maintenance ballot period, all Consensus Group votes and public comments received shall be reviewed by Standards Development staff. A comment determined to be beyond the scope of or clearly not related to the ballot subject matter will be classified as not related and will not be assigned to a Work Group for adjudication. Prior to the Work Group meeting the submitter of the comment declared not related shall be advised in writing of the disposition of the comment and the reason for the classification. Comments declared not related may become, if applicable, recommended actions for the development of a new standard or a revision to an existing standard. In order to verify the submitter's intent, the Data Element Request Form (DERF) process will also be provided to the submitter of the comment to afford them the opportunity to submit a new proposal.

All Other Comments

The responsible Work Group shall review and attempt to resolve all related comments received through the ballot or public review process. All motions for handling said comments shall include an explanation of the reason for the action as follows:

Not Persuasive:

The Work Group adjudicating the comment rejects the changes recommended by the submitter and no changes are made to the standard. Approval of a motion to declare a comment not persuasive shall require an affirmative vote of at least two-thirds of those members present. The submitter of the comment declared not persuasive shall be advised in writing of the classification of the comment and reason for the classification.

Persuasive and Editorial:

The Work Group adjudicating the comment agrees that the comment is persuasive and editorial. Changes recommended by the submitter and approved by the Work Group shall be incorporated into the standard documentation. Approval of a motion to declare a comment persuasive and editorial shall require an affirmative vote of at least two-thirds of those members present. The submitter of the comment declared persuasive and editorial is advised in writing of the classification of the comment and reason for the classification.

Persuasive and Substantive:

The Work Group adjudicating the comment agrees that the comment shall be incorporated into the draft standard as a substantive change. Approval of a motion to declare a comment persuasive and substantive shall require an affirmative vote of at least two-thirds of those members present. The submitter of the comment declared persuasive and substantive is advised in writing of the classification of the comment.

All persuasive and substantive changes to a draft standard after the initial public review shall undergo a subsequent 45 day public and consensus group review in order to afford an opportunity to respond, reaffirm or change a previously presented vote.

H. Public Review

Proposals for new ANS and proposals to revise, reaffirm, or withdraw approval of existing ANS shall be transmitted to ANSI for listing in Standards Action in order to provide an opportunity for public comment. Simultaneous with and in addition to the ANSI public review NCPDP will conduct a public review for NCPDP members who are not part of the Consensus Group. All comments received from these public reviews shall be considered and classified in accordance with section G. Resolution of Comments above.

Public Review comment options are:

1. Accept, with comments. (The commenter may provide comments that are editorial in nature; however, comments are not required.)

2. Object, with reasons. (Objection comments must contain a reason and must be accompanied by documentation that includes specific paragraph, sections, or parts to which the comments pertain, specific substantive reasons for the objection and/or specific wording or actions that, if accepted, would resolve the objection and result in the comment being changed to an accept.)

Public review objectors shall be advised in writing of the disposition of their comment, the reason for the disposition and the right of appeal. The objector may choose to withdraw their objection; otherwise, the response shall be recorded and reported to ANSI as an unresolved objection.

I. Ballot Recirculation

Unresolved objections and attempt at resolution shall be reported to the Consensus Group to afford all members of the Consensus Group an opportunity to respond, reaffirm, or change their original vote through the ballot recirculation. The voting period for a recirculation ballot will be a minimum of 45 calendar days.

New comments received on the re-circulation ballot will not be categorized but may be discussed at the next scheduled Work Group meeting.

After the close of the recirculation ballot, Consensus Group members with unresolved objections will receive written notice of the right to appeal.

J. Public Review Recirculation

Unresolved objections and attempt at resolution shall be reported to the public for an opportunity to respond during the public review recirculation which will be a minimum of 45 calendar days.

New comments received on the public review re-circulation will not be categorized but may be discussed at the next scheduled Work Group meeting.

K. Required Approval

To be approved or adopted, a balloted item must receive at least a 75% approval rate of the affirmative votes and negative votes with reasons.

L. Certification of Standards Data Maintenance Process Results

Once the originating Work Group has reviewed and adjudicated all comments, according to the procedures specified herein, the Board will certify the results. The Board retains final authority over the certification of the results.

M. Announcement of Publication

Once certified by the Board, the final result of each data maintenance ballot will be reported to the membership and general public via a press release, electronic communication or special mailing.

VI. American National Standards

This designation is reserved for standards that have satisfied ANSI requirements to be so designated. ANSI facilitates the development of ANS through the accreditation of procedures used by standards developers and the approval of standards as ANS. Accreditation by ANSI signifies that the procedures used by the standards body in connection with the development of ANS meet the Institute's essential requirements for openness, balance, consensus and due process. The ANSI Board of Standards Review (BSR) approves standards as ANS. ANSI BSR approval of a standard as an ANS is based on evidence of procedural compliance as provided by the standards developer. ANSI approval does not indicate that the ANSI BSR (or any other committee within ANSI) has reviewed the technical content of the document. Rather, approval as an ANS is based on a review of evidence of compliance with accredited procedures, i.e., the process by which the technical content was developed.

A. ANSI Submission and Approval

Approval of an ANS requires verification by ANSI that the standard was developed in accordance with requirements for ANS. Following approval of the ballot, NCPDP staff shall prepare the proper documentation and submit the required forms to the ANSIBSR. Notice of the BSR's final action shall be published in *Standards Action* and announced to the NCPDP membership in suitable media.

B. Process for Discontinuance of a Standards Development Project

At any point prior to submission of a standard for ANS approval, NCPDP staff will notify ANSI of the discontinuance of a reported project. Some examples for discontinuance of a reported project may include:

- Lack of consensus
- No longer needed
- Coordination with another like standard

NCPDP staff will respond to any written request for justification of such an action, as long as received within 60 calendar days of the date of the final action.

C. Maintenance of NCPDP American National Standards

NCPDP Staff shall periodically recommend necessary actions to the Standardization Committee related to transmittal of requests for ANSI approval or revision, reaffirmation, or withdrawal of Council industry standard documents which have been previously accepted as American National Standards. If the actions are favorable, the Standardization Co-Chairs and Council staff shall coordinate necessary Work Group actions, membership ballot preparations and ANSI required procedures to ensure compliance with ANSI requirements, including the requirement for a five year review of all standards to determine if they need to be revised, reaffirmed or withdrawn.

D. Withdrawal of NCPDP American National Standard

NCPDP's Standards Development Department will work with the Standardization Committee regarding a recommendation to withdraw approval of an American National Standard. NCPDP shall notify ANSI and the standard shall be withdrawn as an ANS and announced in *Standards Action*.

E. Interpretation of an NCPDP Standard

A request for interpretation may be submitted by any interested party. The request shall be made in writing and submitted to NCPDP's Standards Development Department. NCPDP will respond to the request for interpretation following the established procedures.

F. American National Standards Policies
1. *Patents*

NCPDP shall adhere to the patent policy stipulated in the current edition of *ANSI Essential Requirements: Due Process Requirements for American National Standards.*

2. *Commercial Terms and Conditions*

NCPDP shall adhere to the restrictions on the use of Commercial Terms and Conditions stipulated in the current edition of *ANSI Essential Requirements: Due Process Requirements for American National Standards*.

3. *Policy on Evidence of Compliance*

Records concerning withdrawn standards shall be retained for at least five years from date of withdrawal. NCPDP records related to new, revised, or reaffirmed American National Standards maintained under the periodic maintenance option shall be retained for one complete standards cycle, or until the standard is revised. Records related to new, revised, or reaffirmed American National Standards maintained under the continuous maintenance option shall be retained for a minimum of five (5) years or until approval of the subsequent revision or reaffirmation of the complete standard.

4. *Metric Policy*

The three units of measure necessary to achieve consistent and accurate billing of pharmaceutical products using NCPDP standards include "each," "grams" and "milliliters."

VII. APPEALS PROCESS

Anyone having a direct and material interest and who has been or might be adversely affected by a standards document, modification of same, or by the lack thereof, will have the right to appeal the substantive content and/or procedural actions or inactions of the Council.

The individual(s) shall submit a written appeal to the President, at the Council. Appeals of substantive content or procedural actions must be filed within 30 calendar days of the date of notification of the action. Appeals of inactions of the Council may be made at any time. The appeal shall state the nature of the objection(s), including any adverse effects; the applicable section(s) of the NCPDP *Bylaws, Standing Operating Procedures* or

the standards that are at issue; the actions or inactions that are at issue; and the specific remedial action(s) that would satisfy the appellant's concerns. Previous efforts to resolve the objection(s) and the outcome of each shall be noted.

Within 30 calendar days of receipt of the appeal, the President or Council staff shall respond in writing to the appellant, specifically addressing each allegation of fact in the appeal and stating how such appeals will be handled. Appeals of substantive content issues, actions or inactions shall be brought to the Standardization Co-Chairs for referral to the Work Group in authority. Appeals based on alleged process violation shall be referred to the Executive Committee. If all steps have been followed and true consensus has been reached at all levels of the standards development process, there should never be an issue that has to be considered by NCPDP's Executive Committee or Board other than final ratification of the proposed standard. Appeals of the data maintenance ballot comment handling shall follow the procedure specified in this document. A decision on the appeal will be rendered to the appellant in writing by the President within 90 business days of receipt of the appeal, stating the findings of fact and conclusion, with the reasoning based on the evidence provided. The appeal may result in any of the following three positions:

1) Finding for the appellant, thereby referring the issue for further action by the Work Group in authority. The findings shall include a specific statement of the issues and facts in regard to which fair and equitable action was not taken and the proposed method of cure.

2) Finding for NCPDP with a specific statement of the facts that demonstrate the fair and equitable treatment of the appellant and the appellant's objections.

3) Finding that new, substantive evidence has been introduced and referring the entire action to the Standardization Co-Chairs, Board and/or Council membership for appropriate reconsideration.

VIII.   AMENDMENT OF STANDING OPERATING PROCEDURES

These *Standing Operating Procedures* may be amended or replaced, or new *Standing Operating Procedures* may be adopted, by the vote of eligible members at any duly organized annual or special meeting of members. It shall be necessary to set forth such proposed amendment, repeal or new *Standing Operating Procedures*, or a summary thereof, in the notice of such a meeting. The Board has the power to approve amendments to the *Standing Operating Procedures* between regularly scheduled general membership meetings. Any changes must be reported at the next such meeting.

IX.   PARLIAMENTARY PROCEDURES

On questions of parliamentary procedure not specifically addressed in these *Standing Operating Procedures*, *Robert's Rules of Order* (latest edition) may be used to expedite due process.

Appendix A: Minutes (Board of Trustees, Committee, Work Group)

Minutes must include the following:

- Name of the group and type of meeting (i.e., Joint Technical Work Group, interim, etc.)
- Date, place and time of meeting
- Co-chair(s) or acting co-chair present
- Time when the meeting was convened
- Notation of approval of the agenda
- Notation of approval of the last minutes
- The agenda topics
- Notation of disposition of each agenda item
- Notation of actions agreed to and resolutions adopted
- Record of all motions and outcomes
- Indication of responsibilities assigned for action
- Time of adjournment
- Designation of the Staff Liaison

A summary of the discussion should be included in the minutes when appropriate. Where appropriate, meeting minutes will be reviewed/approved by the meeting facilitator prior to distribution. The noting of any particular action might be worth recording for historic purposes. The speaker's name and statement must be recorded if a speaker requests that something be shown in the minutes or on the record.

Attachments to the minutes may include

- attendance list
- presentations or other discussion materials