



April 4, 2023

Maureen Connors  
Medicare Drug Benefit and C & D Data Group  
Centers for Medicare & Medicaid Services  
7500 Security Boulevard, C1-24-25  
Baltimore, MD 21244  
Sent via electronic mail

RE: 42 CFR § 423.160 Standards for Electronic Prescribing (b) Standards (5) Formulary and Benefits

The members of the National Council for Prescription Drug Programs (NCPDP) are requesting via an appropriate rulemaking process the adoption of the NCPDP Formulary and Benefit Standard Version 60 in 42 CFR § 423.160 Standards for Electronic Prescribing (b) Standards (5) Formulary and Benefits. The NCPDP Formulary and Benefit Standard Version 60 would replace the currently named NCPDP Formulary and Benefit Standard Version 3.0.

The Formulary and Benefit Standard has been updated to meet industry need and current usage. All files (lists) have been normalized, which allows for smaller files and reusability, and have expiration dates. The alternative and step medication files have been redesigned to reduce file sizes and to include support for reason for use (diagnosis). The step medication files now support a more complex step medication program. Coverage files have been updated to include support for electronic prior authorization and specialty drugs. The copay files have been updated to allow a minimum and maximum copay range without a percent copay. They also support deductibles and pharmacy networks. A comprehensive change log is attached.

The members are also requesting the following timeline be adopted.

- 6 months after the final rule effective date – start of transition period where both versions are allowed.
- 24 months after the final rule effective date – sunset of the Formulary and Benefit Standard Version 3.0.
- 24 months after the final rule effective date – mandated use of the Formulary and Benefit Standard Version 60.

For direct inquiries or questions related to this request, please contact:

Margaret Weiker  
Vice President Standards Development, NCPDP  
[standards@ncdpd.org](mailto:standards@ncdpd.org)  
(480) 477-1000, ext. 170

Sincerely,

A handwritten signature in black ink, appearing to read "William C. Stember". The signature is written in a cursive, flowing style.

Lee Ann C. Stember President & CEO  
National Council for Prescription Drug Programs (NCPDP)  
9240 E. Raintree Drive  
Scottsdale, AZ 85260  
(480) 477-1000 x 108

Attachment: Formulary and Benefit Standard Change Log

## FORMULARY AND BENEFIT STANDARD CHANGE LOG

- Added the following data elements:
  - Alternative Product Groups Link (F45-UU)
  - Alternative Product Groups File ID (F44-UZ)
  - Drug Tier ID (F41-VB)
  - Drug Tier Link (F42-VA)
  - Drug Tier Name (F43-V0)
  - Drug Tier Description (F40-VC)
  - Step Therapy Products ID (F46-UO)
  - Step Therapy Product Groups Link (F47-UL)
- Added the following new data element and values:
  - Deductible Timing (F39-VD)
- Modified the following data element:
  - Message (942-GP) changed length of 150 to 200.
- Removed the following data elements and values from the Standard:

FIELD	NAME OF FIELD
600-64	Change Identifier
C17-6P	Cross Reference File ID
C15-6M	Cross Reference ID
424-DO	Diagnosis Code
492-WE	Diagnosis Code Qualifier
970-JH	RxNorm Qualifier
969-JG	RxNorm Code

- Sunset the following data elements and associated values:

FIELD	NAME OF FIELD
B62-1M	Alternate Product Groups ID
D97-R3	Alternative Product Groups File ID
D92-RU	Approximate Maximum Total Cost
D93-RV	Approximate Minimum Total Cost
C04-1B	Benefit Stage Range End
C05-4Q	Benefit Stage Range End Qualifier
C06-4R	Benefit Stage Range Start
C07-4S	Benefit Stage Range Start Qualifier
C08-4T	Conditional Gender Code
C09-4Y	Conditional Maximum Age Limit

<b>FIELD</b>	<b>NAME OF FIELD</b>
C10-4Z	Conditional Maximum Age Limit Qualifier
C11-5D	Conditional Minimum Age Limit
C12-6H	Conditional Minimum Age Limit Qualifier
989-MF	Formulary Name
C20-6S	General Message Link
C21-6T	Lives Count
C23-6V	Maximum RRA Fill Limit
C24-6W	Maximum Unit Quantity
C27-6Z	Minimum RRA Fill Limit
C28-8V	Minimum Unit Quantity
916-B6	Product Reference Number
917-B8	Product Reference Number-Alternative
919-CS	Product Reference Number-Source
921-CU	Product Reference Number-Step Therapy Product
916-B7	Product Reference Qualifier
918-B9	Product Reference Qualifier-Alternative
920-CT	Product Reference Qualifier-Source
922-CV	Product Reference Qualifier-Step Therapy Product
D94-R0	Quantity Related To Total Cost
E05-S0	Step Therapy Product Groups File ID
C45-9R	Step Therapy Products File ID
C44-9Q	Step Therapy Product Groups ID

- Added, modified or sunset values for the following data elements:
  - Formulary Status (927-FP)
  - Non-Listed Brand Over The Counter Formulary Status (948-GV)
  - Non- Listed Generic Over The Counter Formulary Status (949-GW)
  - Non- Listed Medical Supplies Formulary Status (950-GX)
  - Non- Listed Multi-Source Brand Formulary Status (C31-8Y)
  - Non-Listed Prescription Generic Pharmacy Status (947-GU)
  - Non-Listed Single Source Brand Formulary Status (946-GT)
  - Product Type (964-JA)
  - Pharmacy Type (955-HR)

- Record Type (601-04)
- Updated the following sections:

Section #	Title	Modification
1.1	Document Scope	Add the Formulary And Benefit Examples Guide and updated the language for the NCPDP Formulary And Benefit Operating Rules
4.1	Introduction	Updated Figure 2.
4.2	Formulary & Benefit Data Overview	Removed reference to Cross Reference File
4.2.1	Formulary Status	Removed On Formulary for the status of "B"
4.2.2	Alternatives	Added additional guidance on the concept of preferred and preference level
4.2.3	Coverage Information	Updated Messaging.
4.2.4	Copay Information	Added additional information on the copay terms that are communicated to the technology system vendors
	Cross-Reference Information	Removed Section
4.4.1	Representative NDC	Updated guidance.
	RxNorm	Removed section.
5	File Processing Guidance	Updated guidance.
5.2	Flow Two: Presenting Product Copay	Updated guidance on presentation of copay terms for each type of pharmacy. Removed #8 Display the copay message if associated to the copay summary file heard or copay summary detail records AND there is not a PE record. If both copay messages are present, the detail copy message takes precedence over the PE message.
5.3	Flow Three Presenting Alternative	Added if populated to 4b. Removed reference to the Cross Reference ID (C15-6M). Removed reference to Product Reference Number Source (919-CS). Updated Alternative Product Groups ID (B62-1M) to Alternative Product Groups Link (F45-UU).
5.4	Flow Four Processing Pharmacy Network Status	Removed reference to the Cross Reference file.
6	File Processing Options	Updated benefit file to benefit file sets.
6.1	Update Date Process	Updated that file to that record and removed Deleting a File Set figure causing remaining figures numbers to be updated. Removed guidance on the use of "D" (Delete) in the file header.
7.1	Transmission Level From The Sender To The Receiver	Updated Figure 9 to reflect new data element names.
8.1.1	File Header/Trailer Definition	Removed "A formulary file consists of formulary, alternatives, benefit coverage and benefit copay file types and a cross reference file.
8.1.2	Formulary And Benefit File Header	Updated Version/Release Number to 60. Updated comments on Transmission Date and Transmission Time
	Cross Reference File	Removed Section and sub-sections causing all remaining sections to be renumbered.
8.2.1	Formulary Status Header	Removed Formulary Name (988-MF). Updated comment for File Effective Date (929-FZ) and File Expiration Date (B93-3Y). Removed Message Link (C26-6Y).
8.2.2	Formulary Status Detail	Removed requirement for Product/Service ID.

		Added Deductible Timing (F39-VD). Removed Change Identifier (600-64).
8.2.2 8.4.2.2 8.5.3.2 8.5.4.2 8.5.7.2.2	Formulary Status Detail Copay Product Specific Detail Gender Limits Detail Prior Authorization Detail Step Therapy Product Groups Detail	Corrected Reason For Use Qualifier ID.
8.2.4	Drug Tier Header	New section and layout.
8.2.5	Drug Tier Detail	New section and layout.
8.2.6	Drug Tier Trailer	New section and layout.
8.3.1.1	Alternative Products Triggers Header	Updated comment for File Effective Date (929-FZ) and File Expiration Date (B93-3Y).
8.3.1.2	Alternative Product Triggers Detail	Removed requirement for Product/Service ID. Updated Alternative Product Groups ID (B62-1M) to Alternative Product Groups Link (F45-UU).
8.3.2.1	Alternative Product Groups Header	Updated comment for File Effective Date (929-FZ) and File Expiration Date (B93-3Y). Updated Alternative Product Groups File ID (D97-R3) to Alternative Product Groups ID (F44-UZ).
8.3.2.2	Alternative Product Groups Detail	Removed requirement for Product/Service ID. Removed Change Identifier (600-64). Added Values: See External Code List to the comments for Formulary Status Override (D98-R4). Updated Alternative Product Groups ID (B62-1M) to Alternative Product Groups Link (F45-UU).
8.4.1.1	Copay Summary Header	Updated comment for File Effective Date (929-FZ) and File Expiration Date (B93-3Y).
8.4.1.2	Copay Summary Detail	Added Deductible Timing (F39-VD) and added whole number in the comments for Formulary Copay Price Point (C16-6N). Removed Change Identifier (600-64). Updated requirement for First Copy Tier (924_DH). Updated Type for Copay Range Type (D64-RP).
8.4.2.1	Copay Product-Specific Header	Updated comment for File Effective Date (929-FZ) and File Expiration Date (B93-3Y).
8.4.2.2	Copay Product-Specific Detail	Removed requirement for Product/Service ID. Added Deductible Timing (F39-VD). Updated Requirement for Percent Copay Rate (954-HQ). Correct Section Name.
8.5.1.1	Product Exclusion Header	Updated comment for File Effective Date (929-FZ) and File Expiration Date (B93-3Y).
8.5.1.2	Product Exclusion Detail	Removed requirement for Product/Service ID. Removed Change Identifier (600-64).
8.5.2.1	Age Limits Header	Updated comment for File Effective Date (929-FZ) and File Expiration Date (B93-3Y).
8.5.2.2	Age Limits Detail	Removed requirement for Product/Service ID and Product Reference Number. Removed Product Reference Number (915-B6) and Product Reference Qualifier (916-B7). Updated requirements for Minimum Age Qualifier (943-GQ) and Maximum Age (932-GA). Add Reason for Use Code (D99-R5).
8.5.3.1	Gender Limits Header	Updated comment for File Effective Date (929-FZ) and File Expiration Date (B93-3Y).
8.5.3.2	Gender Limits Detail	Removed requirement for Product/Service ID. Removed Change Identifier (600-64).

8.5.4.1	Prior Authorization Header	Updated comment for File Effective Date (929-FZ) and File Expiration Date (B93-3Y).
8.5.4.2	Prior Authorization Detail	Removed requirement for Product/Service ID.
8.5.5	Quantity Limits File (QL)	Moved from previous Section of 8.6.4
8.5.5.1	Quantity Limits Header	Updated comment for File Effective Date (929-FZ) and File Expiration Date (B93-3Y).
8.5.5.2	Quantity Limits Detail	Removed Change Identifier (600-64).
8.6.6.1	Specialty Products Header	Updated comment for File Effective Date (929-FZ) and File Expiration Date (B93-3Y).
8.5.6.2	Specialty Products Detail	Removed requirement for Product/Service ID. Removed Change Identifier (600-64).
8.5.7.1.1	Step Therapy Products Header	Updated comment for File Effective Date (929-FZ) and File Expiration Date (B93-3Y). Updated Step Therapy Products File ID (C45-9R) to Step Therapy Products ID (F46-UO).
8.5.7.1.2	Step Therapy Products Detail	Removed requirement for Product/Service ID. Removed Change Identifier (60-64). Corrected the Name of Product/Service ID Qualifier – Source (963-HZ). Updated Step Therapy Product Groups ID (C44-9Q) to Step Therapy Product Groups Link (F47-UL).
8.5.7.2.1	Step Therapy Groups Header	Updated comment for File Effective Date (929-FZ) and File Expiration Date (B93-3Y). Updated Step Therapy Product Groups ID (C44-9Q) to Step Therapy Product Groups Link (F47-UL).
8.5.7.2.2	Step Therapy Product Groups Detail	Added Reason For Use Action. Corrected Field Number for Formulary Status Override. Removed requirement for Product/Service ID – Step Therapy Product. Removed Change Identifier (600-64). Updated Step Therapy Product Groups ID (C44-9Q) to Step Therapy Product Groups Link (F47-UL).
8.6.1.1	Pharmacy Chain Header	Updated comment for File Effective Date (929-FZ) and File Expiration Date (B93-3Y).
8.6.2	Pharmacy Network Header	Removed values from Comments for Non-Listed Retail Pharmacy Status (C32-8Z), Non-Listed Mail Order Pharmacy Status (C30-8X), Non-Listed Specialty Pharmacy Status (C33-9B) and Non-Listed LTC Pharmacy Status (C29-8W). Updated comment for File Effective Date (929-FZ) and File Expiration Date (B93-3Y).
8.6.2.2	Pharmacy Network Detail	Removed values from Comments for Pharmacy Network Status (C38-9H).
8.7.1.1	General Message Header	Updated comment for File Effective Date (929-FZ) and File Expiration Date (B93-3Y). Removed Message Link (C26-6Y) and replaced with General Message ID (C19-6R).
8.7.1.2	General Message Detail	Removed requirement for Product/Service ID.
8.7.2.1	Message Header	Updated comment for File Effective Date (929-FZ) and File Expiration Date (B93-3Y).
8.7.2.2	Message Detail	Increased size of Message from 150 to 200. Correct the field name and ID in the comments for Message (942-GP) and URL (987-MA).
9.1.1	Formulary and Benefit Response File Header	Updated comment for File Effective Date (929-FZ), File Expiration Date (B93-3Y), Transmission Date – Originating and Transmission Time - Originating.

12.2	Overview	Updated guidance.
12.3	Separator Characters	Updated example.
12.3.1	Separator Character Rules	Update guidance.
12.7.1.1	Numeric Truncation	Updated guidance.
13	Transmission Examples	Updated guidance and moved examples to the Version 60 Formulary And Benefit Examples Guide.
	Frequently Asked Questions	Removed from Imp Guide will add to recommendations document.