Background and Guidance for Using the NCPDP Standards for Digital Therapeutics

Version 1.1

This document provides guidance on the use of NCPDP Standards for the ordering and fulfillment of Digital Therapeutic products and services.

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1. INTRODUCTION

This document provides guidance on the use of NCPDP Standards for the ordering and fulfillment of digital therapeutic products and services. This document's intent is to facilitate electronic data exchange between digital therapeutic trading partners, enabling patient access to digital therapeutics.

1.1 DOCUMENT SCOPE

This document identifies those additional criteria or requirements for digital therapeutic products and services within NCPDP standards beyond that described in the published standards documents. This document does not address all NCPDP standards, only those where an implementer may anticipate digital therapeutics specific requirements exist.

1.1.1 TASK GROUP APPROACH TO SCOPE

There are multiple potential use cases for the ordering and fulfillment of a digital therapeutic product or service for a patient. The Digital Therapeutics Task Group was charged with evaluating NCPDP standards, however, the applicability of an existing standard may be dependent on the actual digital therapeutics use case.

Therefore, the task group began by evaluating standards for the specific use case that was initially brought forth to NCPDP. After the task group has completed their analysis of the standards and their applicability for the initial use case, the NCPDP standards will then be evaluated for other use cases brought forth to the task group. This will be done by re-evaluating the standards in light of the manner in which the new use case varies from the initial use case.

Industry is encouraged to bring their use cases to the task group for prioritization and evaluation.

1.2 NCPDP AND RELATED STANDARDS

The following NCPDP and related standards are addressed in this document. Users of this document should consult the implementation guides for further information and details on the standards. Refer to [Section 3 Standards Review](#) for information on where to access implementation guides.

- Billing Unit Standard
- Product Identifiers Standard
- Telecommunication Standard
- SCRIPT Standard
- Formulary and Benefit Standard
- Real-Time Prescription Benefit (RTPB) Standard
- X12 835 Health Care Claim Payment/Advice
- Benefit Integration Standard

1.3 INTENDED AUDIENCE

The intended audience of this guidance document includes, but is not limited to:

- Digital therapeutics manufacturers
- Prescribers / Health Systems
- Electronic Health Record (EHR) vendors

- Hub service providers
- Pharmacies
- Payers (Health Plans, Employers, Accountable Care Organization (ACO), Integrated Delivery Networks (IDNs))
- Claims Processors / Pharmacy Benefit Managers (PBMs)
- Intermediaries

2. BACKGROUND

2.1 DIGITAL HEALTH AND DIGITAL THERAPEUTICS

The use of technology is transforming the ecosystem of healthcare. In recent decades the uses of telemedicine, remote monitoring devices, smart medical devices and the use of wearables has made significant advances in the delivery of healthcare. The advent and ubiquitous nature of smartphones, watches and tablets has facilitated a new era of medicine that not only leverages hardware-based interventions, but also software-based technologies to monitor, modify, treat and improve diseases and conditions. Many of these new technologies fall under the larger umbrella of "digital health." Within digital health fall the categories of "digital medicine" and "digital therapeutics." Based on the literature, digital medicine and digital health products may be used more for measurement, assessment, patient engagement, clinical decision making of medical conditions and diseases. As opposed to other digital health categories, digital therapeutics have the capability to treat, manage, and prevent diseases and conditions. The Digital Therapeutics Alliance (DTA), an industry trade organization focused on the space, provides the following definition of digital therapeutics:

> *Digital therapeutics (DTx) deliver evidence-based therapeutic interventions that are driven by high quality software programs to prevent, manage, or treat a medical disorder or disease. They are used independently or in concert with medications, devices, or other therapies to optimize patient care and health outcomes.*

Within the larger paradigm of digital health, digital therapeutics face some unique issues, especially for those who pursue Food and Drug Administration (FDA) clearance.

2.1.1 DIGITAL THERAPEUTICS USE IN HEALTH CARE INDUSTRY - BUSINESS FUNCTIONS

Digital therapeutics are transforming the way medical conditions are diagnosed, treated, managed and prevented. A growing body of evidence supports the safety and efficacy of these treatment modalities and justifies their recognition as reasonable and necessary therapies across patient populations and disease areas. Digital therapeutics have been created to deliver new disease treatment and management methods, teach new coping skills and report progress to those caring for patients. Digital therapeutics are also creating new avenues to help manage disease and augment medications, such as a sensor and application that may improve patient adherence when used with traditional therapy. Other digital therapeutic products and services have the potential to replace medication with cognitive behavioral therapy or software programs that directly activate physiology to achieve clinical outcomes. In addition, several software-based programs have specifically demonstrated they are more effective than alternative therapies in terms of clinical outcomes and user experience. Over the last decade, and in increasing frequency over the past few years, digital therapeutics have received marketing authorization from the FDA by demonstrating safety and effectiveness through validation, bench testing and clinical trial/real world evidence generation. During this period, FDA created several new classifications for devices under the "De Novo process" for brand new software technologies—with many more under development or in the FDA review pipeline. During this same time period, the value of partnerships and public offerings of digital health and therapeutics companies rose into the billions of dollars. Combining these factors with the relatively rapid development and validation cycle compared to pharmaceuticals, leads to a conclusion

that digital therapeutics are poised to see the number of companies with FDA clearance expand rapidly in the near future.

2.2   STANDARDS BASED BUSINESS NEEDS IN DIGITAL THERAPEUTICS

Digital therapeutics face a unique set of challenges due to their virtual nature. Furthermore, some face additional constraints in terms of processing and distribution as a result of their classification as prescription medical devices. How is it possible for a product without a physical component to be prescribed, distributed, dispensed and processed by all the necessary stakeholders in the prescription drug ecosystem? This includes, but is not limited to, providers, health systems, claims processors, compendia, hubs, pharmacies and digital therapeutic manufacturers. How can these products fit into the ecosystem and leverage their virtual nature without examining the applicability of both NCPDP standards and external standards used to support data exchange?

2.2.1   BILLING AND REIMBURSEMENT BACKGROUND

Digital therapeutics are already in wide use. They are utilized in both clinical practice and for at-home use. Regardless of the site of care, when these products are submitted to the FDA for review or qualify based on their intended use, they are classified as medical devices. Digital therapeutics cleared by the FDA receive Unique Device Identifiers (UDI). Unique device identifiers serve several valuable purposes as outlined by the FDA, however, the UDI is not widely used today under the pharmacy benefit for billing and reimbursement purposes.

Prior to September 2018, medical device manufacturers were permitted to label their products with a National Health Related Items Code (NHRIC) or the National Drug Code (NDC), which could be utilized similarly to the purpose of the UDI code and for pharmacy billing and reimbursement purposes. However, for products labeled after September 2018, this practice is no longer allowed. Medical devices (durable medical equipment (DME), medical & surgical supplies, feeding supplies, etc.) are primarily billed and reimbursed utilizing the Center for Medicare and Medicaid Services (CMS) alpha numeric Healthcare Common Procedure Coding System (HCPCS). There is presently no existing HCPCS category for digital therapeutic billing. Therefore, industry faces some challenges in the processing and reimbursement of the digital therapeutic via existing pharmacy, claims processor, and payer workflows.

Despite the similarities in the workflows to prescription drugs, digital therapeutics have not been able to leverage the advanced systems and processes utilized by the prescription benefit ecosystem. During this time of transition when traditional medical device HCPCS coding remains unused by those billing and processing under the prescription benefit, products billed under that benefit are able to acquire "National Drug Code (NDC)-like" coding. In order to fit into the prescription benefit workflows however, digital therapeutics still have required handwritten prescriptions, faxes and telephonic interactions between prescribers, pharmacies, patients, manufacturers, health plans and PBMs.

The present state environment and "as is" situation is not scalable and is unsustainable for the industry.

2.3 NCPDP TASK GROUP

2.3.1 FORMATION OF TASK GROUP

In response to these issues and requests from the digital therapeutics industry, in 2018 NCPDP created a Digital Therapeutics Task Group within the Maintenance and Control (MC) Work Group. The task group was created to assess if and how digital therapeutics can fit into existing workflows for pharmacies, payers, processors and clinicians. Specifically, the task group was formed to determine if these products can participate in electronic data exchange between stakeholders within the prescription benefit by evaluating the existing NCPDP and other standards used and by determining any support or modifications needed to process digital therapeutics in a manner similar to prescription medication. Through the work of the task group, electronic data exchange between these digital therapeutics stakeholders will be better supported and patient access to digital therapeutics improved.

2.3.2 PHARMACY FULFILLMENT AND BILLING OF PRESCRIPTION DIGITAL THERAPEUTIC (INITIAL USE CASE)

The task group developed an approach to evaluation by considering the initial use case brought to NCPDP by the digital therapeutics industry. The characteristics of that initial use case are described below:

- The digital therapeutic has been cleared by FDA through 510(k) Pre-Market Notification, Pre-Market Approval Application (PMA) or granting of a De Novo classification request.
- The digital therapeutic is available to a patient only upon the prescription order of a licensed health care provider.
- The prescription and resulting claim must comply with the NCPDP Billing Unit and Product Identifiers Standards (described in sections 3.1 and 3.2 below).
- The product is fulfilled in the pharmacy setting, including community, specialty and long-term care, for the patient's use in a way similar to that of a prescribed medication.
- Fulfillment may or may not include the provision of a physical product, patient specific information such as a product activation code, educational materials, instructions for use or pharmacy professional services related to the digital therapeutic.

Although there may be some exceptions, the initial use case assumes the digital therapeutic is covered under the patient's outpatient prescription drug benefit and should be billed to the appropriate payer or processor. There are some instances where pharmacies bill for products fulfilled or administered by a pharmacy/pharmacist that are covered under the patient's medical benefit, but the process generally requires an intermediary or other billing methodology and is more complex. The task group has not yet analyzed use cases where the product fulfilled by the pharmacy is billed to the patient's medical benefit.

The diagram below reflects the touch points in the business process where the use of NCPDP standards is most relevant.
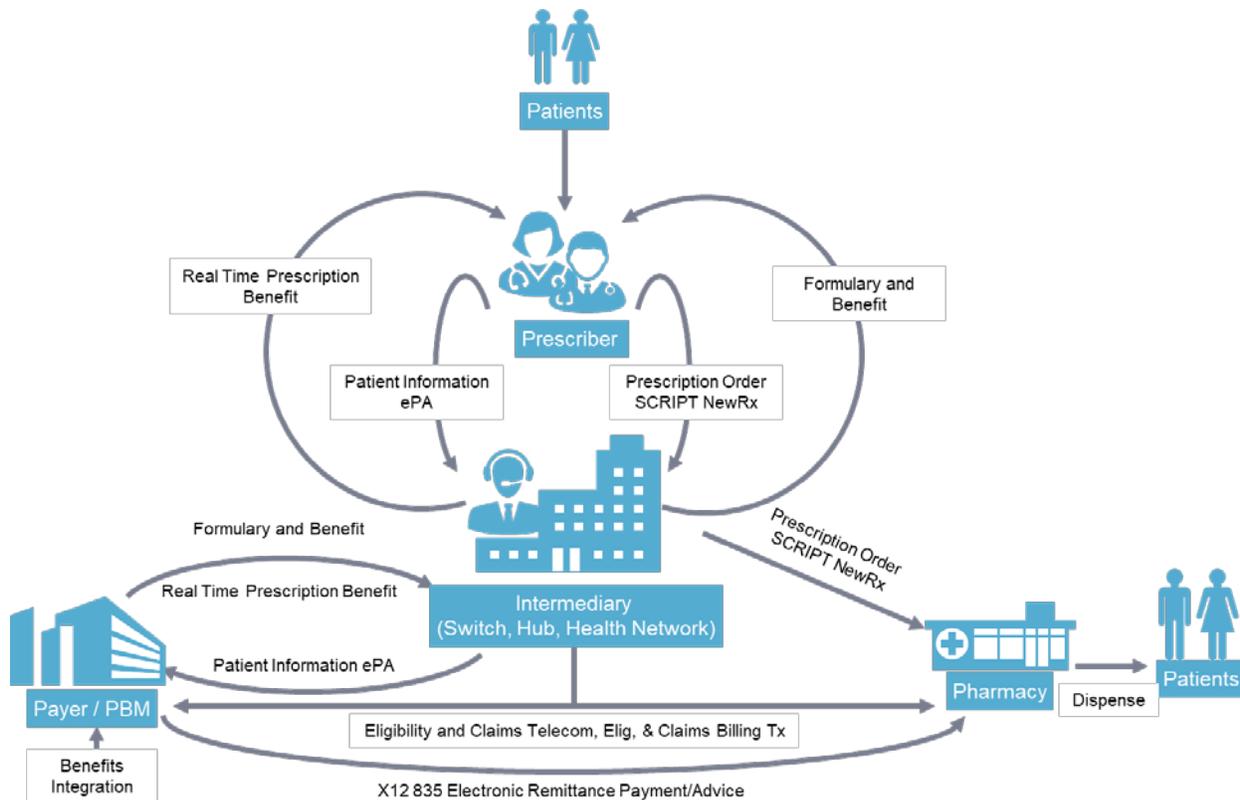
Figure 1

In the business process flow above (Figure 1), the provider verifies the digital therapeutic is covered by the patient's prescription benefit (using the Formulary & Benefit Standard and/or RTPB Standard) and then initiates the order. If the product selected requires an authorization by the payer, the provider may send an electronic prior authorization (ePA) request to the payer using the NCPDP SCRIPT ePA transaction and subsequently respond to the payer's question set electronically in real time. Once approved, the prescription order can then be transmitted electronically to a participating pharmacy of the patient's choice using the NCPDP SCRIPT NewRx transaction. These electronic transmissions are typically routed between the sender and receiver via an intermediary.

At the pharmacy, the pharmacy personnel fill the prescription order and send a claim transaction to the PBM using the NCPDP Telecommunications Standard Claim Billing Request. In some instances, the pharmacy may have the option to determine the patient's plan eligibility status before submitting a claim by using the NCPDP Telecommunication Standard Eligibility transaction; however, eligibility will always be determined as part of the claim billing adjudication process.

The PBM sends back their results of claim adjudication and notifies the pharmacy of either a paid or rejected status in the NCPDP Telecommunication Standard Claim Billing Response. The response contains information specific to the claim payment or reason for rejection of the claim. If the claim is paid (i.e., approved), the pharmacy personnel fill the prescription and collect the appropriate copayment from the

patient. The pharmacy is reimbursed for the claim by the payer who also issues an electronic remittance advice utilizing the X12 835 Health Care Claim Payment/Advice.

2.3.2.1 NCPDP STANDARDS POTENTIALLY UTILIZED BY THE INITIAL USE CASE

The task group identified the NCPDP standards that are used in the initial use case brought forward to NCPDP. The standards and data transactions were then prioritized based on their importance to digital therapeutics manufacturers, pharmacies, payers, processors/PBMs and other trading partners to facilitate adoption and successful completion of all transactions.

NCPDP and related standards identified as "high importance" for the task group review are:

1. Billing Unit Standard
2. Product Identifiers Standard
3. SCRIPT Standard
4. Telecommunication Standard
5. Formulary and Benefit Standard
6. Real Time Prescription Benefit (RTPB) Standard
7. Specialty Pharmacy Data Reporting Standard
8. Benefit Integration Standard
9. Medical Rebate Data Submission Standard
10. Manufacturer Rebate Standard
11. XML Standard
12. X12 835 Health Care Claim Payment/Advice

2.3.3 STANDARDS REVIEW

The task group determined the standard transactions in 2.3.2.1 above to be initially reviewed were the ones related to writing an electronic prescription and submitting a claim.

The names and versions of the standards reviewed for usability were:

- Billing Unit Standard Version 3.1
- Product Identifiers Standard Version 1.4
- Formulary and Benefit Standard Versions 3.0 and 53
- RTPB Standard Version 11
- SCRIPT Standard Version 2017071
- Telecommunication Standard Versions D.0 and F6
- X12 835 Health Care Claim Payment/Advice 005010X221A1
- Benefit Integration Standard Version 16

The review assumed the initial use case brought to the Task Group which includes all of the following components:

- The patient is eligible under the health plan
- The product is covered under the patient's prescription benefit

- Prior authorization (if necessary) is obtained
- A prescription order is electronically sent to the pharmacy
- The pharmacy submits a claim to the PBM for the patient's prescription benefit plan
- The pharmacy fulfills the prescription order

If any of the steps in the process flow above are omitted (for example, the digital therapeutic is covered under the medical benefit or, the digital therapeutic does not require the pharmacy to fulfill a prescription order), then the use case does not qualify under the Task Group's initial use case under which the 4 standards named above were reviewed.

The Task Group is continuing its review of the standards remaining on the list in 2.3.2.1 above. Any potential modifications that may be necessary to the standards or this guidance will be identified.

2.3.4 FUTURE USE CASES

Going forward, additional use cases (other than the initial use case) brought forth to NCPDP by the industry will be reviewed by the Digital Therapeutics Task Group for suitability of information exchange using NCPDP standards. If no NCPDP standard exists to satisfy use cases brought forward to the task group, NCPDP will consider developing a standard to satisfy the use case. Prior to developing any new standard, the task group will identify whether other ANSI-accredited Standards Development Organizations have an industry adopted standard that should be reviewed by that SDO for possible applicability.

3.   STANDARDS REVIEW

NCPDP standards cover many business processes that occur in the prescription drug benefit ecosystem. The standards are used by industry participants including commercial and government payers/health plans, manufacturers, wholesalers, hubs, physician/prescribers, pharmacies and pharmacists, intermediaries, data aggregators, compendia and health networks. This guidance document is focused on standards used in the authorization and prescribing of a digital therapeutic and its fulfillment by a pharmacy for billing under the patient's outpatient prescription benefit.

The **NCPDP SCRIPT NewRx** transaction is the primary e-prescribing transaction. As part of the new prescription process, the prescriber may review the patient's prescription benefit formulary, limitations, patient copays and other information related to selection of therapy using the **NCPDP Formulary and Benefit Standard** and/or the **RTPB Standard**. The prescriber then selects the therapy for the patient and indicates product and quantity, patient instructions (Sig) and other related information (refills, patient information). If the product selected requires an authorization by the payer, the prescriber may send an electronic prior authorization (ePA) request to the payer using the **NCPDP SCRIPT PA** transactions and subsequently respond to the payer's question set electronically in real-time, to obtain authorization. Once approved, the prescription is transmitted electronically to the participating pharmacy of the patient's choice using the **NCPDP SCRIPT NewRx** transaction. This electronic transmission is typically routed from the sender to the receiver via an intermediary such as a "switch" or "health information network."

At the pharmacy, the pharmacy personnel fill the prescription order and send a claim transaction to the PBM using the **NCPDP Telecommunications Standard Claim Billing *Request***. In some instances, the pharmacy may have the option to determine the patient's plan eligibility status before submitting a claim by using the **NCPDP Telecommunication Standard *Eligibility*** transaction; however, eligibility will always be determined as part of the claim billing adjudication process.

The processor/PBM then sends back a decision, or "adjudication," of the claim notifying the pharmacy of either a "paid" or a "rejected" claim in the **NCPDP Telecommunication Standard Claim Billing *Response*** transaction. The response contains information specific to the claim payment or reason for rejection of the claim. If the claim is a "paid" claim, the pharmacy personnel fill the prescription order and collect the appropriate patient responsibility amount.

Finally, the pharmacy receives payment for the product and services and is provided detail on the payment from the payer using the X12 835 Health Care Claim Payment/Advice.

Users of this document should consult the NCPDP documents related to the standards analyzed and listed in Section 2, including the relevant Implementation Guides, Editorial Documents, Data Dictionaries and External Code Lists for further information and clarification. These documents are available to NCPDP members via the Standards Lookup Tools menu option on the [MyNCPDP™](#) website. NCPDP membership provides access to all NCPDP Standards. Non-members may obtain the documents by becoming NCPDP members. For more information, please see [www.ncpdp.org](#) or contact the NCPDP office at 480-477-1000, or via e-mail at [ncpdp@ncpdp.org](#).

If industry participants find business needs not fulfilled by the following review of standards and transactions, please contact the Council office for information on how to bring forth proposed changes to the transactions to the Digital Therapeutics Task Group.

3.1 NCPDP BILLING UNIT STANDARD

The NCPDP Billing Unit Standard Implementation Guide provides guidelines for consistent implementation of drug/product packaging for use in all applicable NCPDP Standards. The standard transactions addressed in this document require compliance with the NCPDP Billing Unit Standard. This standard provides guidelines and a "common billing unit language" for use in all applicable NCPDP Standards adding consistency in implementation of drug/product packaging.

The NCPDP Billing Unit Standard was developed to achieve the following:

- To be simple and easy to use
- To utilize good business sense
- To standardize what is already used by the majority of the drug delivery industry
- To minimize exceptions
- To add value and clarification for all who use pharmaceutical product data

The guiding principle of the standard is there are only three billing units necessary to describe all drug products. The billing units are as follows:

- "each" – abbreviated as "EA" in the context of the Billing Unit Standard
- "mL" or milliliter – abbreviated as "ML" in the context of the Billing Unit Standard
- "gm" or gram – abbreviated as "GM" in the context of the Billing Unit Standard

Goals of the NCPDP Billing Unit Standard are:
- Consistent and accurate billing of products
- Common agreement on the application of the Billing Unit Standard by the industry
- Elimination of under- and over- payment of a claim

Billing unit questions and issues should be brought to the NCPDP Work Group 2 Product Identification using a Quantity Unit Information Communication (QUIC) form for discussion and adjudication. Blank QUIC forms and adjudicated QUIC forms can be found on the NCPDP web site (https://standards.ncpdp.org/Billing-Unit-Request.aspx).

3.1.1 APPLYING THE BILLING UNIT STANDARD TO THE INITIAL USE CASE

What is the billing unit for a digital therapeutic in the initial use case (as defined in Section 2.3.2)? Since a digital therapeutic is likely not to be a measurable product, it will most frequently be classified as an EACH. The pharmacy is dispensing the authorization to use the digital therapeutic. In this case, an activation code. The right to use the product upon a medical provider's order may or may not be for a finite time of the therapy. If, for a time period, the quantity of 1 each may be a 30-day supply as an example. Therefore, by applying the billing unit "each" for the initial use case, an activation code for the digital therapeutic

provided by the pharmacy to the patient gives authorization to use the digital therapeutic for the duration determined by the provider or manufacturer.

3.1.2 DETERMINING THE BILLING UNIT FOR DIGITAL THERAPEUTIC PRODUCTS

As new digital therapeutics are created, the task group recommends that manufacturers contact NCPDP in the initial phase of market development (i.e., at the point when "packaging" and labeling begins, continuing to the market entry date) to assist in the determination and/or validation of billing units.

Items to consider when applying the NCPDP Billing Unit Standard:
- Precedence and perception in the industry
- The product identifier code (NDC, Universal Product Code (UPC) or Unique Device Identifier (UDI)) in the 11-digit format defined in the NCPDP Product Identifier Standard.
- How is the "dispenser" going to submit this digital therapeutic on a claim?
- How is the digital therapeutic going to be prescribed?
- How is the digital therapeutic going to be dispensed?
- Is there a package and can it be broken or split?
- Billing of digital therapeutic at the point of dispensing
- Product labeling
- Patient and clinician understanding
- Quantity description. What is received by the patient?
- Any impact on rebate systems
- Any impact on claims adjudication

The QUIC form is used to request clarification of and/or suggest modifications to the NCPDP Billing Unit Standard. Blank QUIC forms and adjudicated QUIC forms can be found on the NCPDP web site (https://standards.ncpdp.org/Billing-Unit-Request.aspx). QUIC forms should be submitted 30 days prior to the next Work Group meeting.

NCPDP members can obtain the NCPDP Billing Unit Standard Implementation Guide under Standards Lookup Tools on the MyNCPDP™ website. Work Group 2 Product Identification is responsible for updating the NCPDP Billing Unit Standard Implementation Guide. Questions should be directed to WG2 Product Identification.

3.2 NCPDP PRODUCT IDENTIFIERS STANDARD

The goal of this standard is to ensure any change to critical product identifiers is managed in a way that does not adversely affect patient safety, financial processes involving products and the healthcare applications that currently use these identifiers.

The following identifiers are accepted in the NCPDP standards for products.

- NDC*
- UPC*
- National Health Related Item Code (NHRIC)*

- • Device Identifier (DI) portion of the UDI*
- • Global Trade Identification Number (GTIN)
- • Health Industry Business Communications Council® Code (HIBCC®) (19-digit limit)
- • Product Identification Numbers (PIN)*

The referenced identifiers above are those used in product labeling. The list does not show all of the identifiers used within all of the NCPDP Standards. For a complete list, please see the Product/Service Qualifier Shared Code List of the External Code List.

* Identifiers specifically listed in the NCPDP Telecommunication Standard and SCRIPT Standard.

3.2.1 FORMATS

For this initial use case, digital therapeutic manufacturers are required to obtain a GTIN or HIBCC product identifier code. NCPDP provides guidance on how to reformat the above identifiers to a NCPDP formatted identifier. The reformatted identifier functions as product specific code and allows for digital therapeutics to utilize NCPDP standards between prescribers, pharmacies and processors/PBMs. This includes applying the reformatted number for use in NCPDP SCRIPT (e.g., NewRx and PA messages) and NCPDP Telecommunications (e.g., Claims Billing transaction). See Sections 3.3 and 3.4 for applicable standards.

NCPDP members can obtain the NCPDP Product Identifiers Standard Implementation Guide under Standards Lookup Tools on the MyNCPDP™ website. Work Group 2 Product Identification is responsible for the NCPDP Product Identifiers Standard Implementation Guide. Questions should be directed to WG2 Product Identification.

3.3 NCPDP FORMULARY AND BENEFIT STANDARD

Prescriber Reviewing Patient's Plan Formulary and General Benefit Information

3.3.1 INTRODUCTION TO FORMULARY AND BENEFIT FILES

This NCPDP Formulary and Benefit Standard provides a standard means for pharmacy benefit payers (including health plans and PBMs) to communicate formulary and benefit information to prescribers via technology vendor systems. The purpose of the standard is to provide various kinds of information to the prescribers to inform their decision on choice of various drug or digital therapeutic therapies for the patient.

Information includes:

- which products are considered to be "on formulary" and alternative products for those products not on the plan's formulary.
- limitations that may impact whether the patient's benefit will cover a product being considered (such as age limits, gender limits, step therapy rules, benefit-specific coverage exclusions, etc.)
- cost of therapy to the patient (e.g., copays) for one product option versus another.

The Formulary and Benefit Standard consists of a set of files that contain data regarding the patient's prescription benefit plan. The Summary Information Model in Appendix A illustrates the types of information contained in the files.

Payers create, publish and maintain a formulary which is a list of drugs/products covered in the prescription drug benefit and the coverage limitations, exclusions and patient copayments associated with each product on the formulary.

> ### NCPDP Formulary and Benefit Standard
>
> *The Task Group found no data elements to be missing for a digital therapeutic and no information required by the any of the Formulary and Benefit files that would prevent the required information from being included when the relevant product is a digital therapeutic complying with Use Case One.*

Formularies are updated by payers on a routine basis. This formulary information as well as information on pharmacies included in the payer's network are part of the information e-prescribing technology vendor systems typically provide to prescribers when making a therapy choice prior to prescribing. Payers provide these technology vendors with this information using the NCPDP Formulary and Benefit Standard.

It is important to note that the Formulary and Benefit files are "batch files" that are created by payers and transferred to technology system vendors who use these files to maintain information on the payer's various formularies for the prescriber. The files are specific to the benefit plan, but not to a specific covered person or patient. For patient specific benefit information, the prescriber must utilize the NCPDP RTPB Standard transactions. See Section 3.4.

3.3.2 TASK GROUP ANALYSIS OF FORMULARY AND BENEFIT FILES AND CONCLUSIONS

When reviewing the NCPDP Formulary and Benefits Standard the task group found no required data elements to be missing if digital therapeutic coverage information was added to the Formulary and Benefit files sent by the payer. However, in order to be included, a digital therapeutic product *must also comply with* the NCPDP Product Identifier and Billing Unit Standards. See Section 3.2.

3.4 NCPDP REAL-TIME PRESCRIPTION BENEFIT (RTPB) STANDARD
Provider Identifying Patient Specific Benefit and Copayment Information

The RTPB Standard enables the exchange of patient eligibility, product coverage and benefit financials for a chosen product and pharmacy and identifies coverage restrictions and alternatives when they exist.

3.4.1 INTRODUCTION TO RTPB STANDARD

Prior to the development of the RTPB Standard, patients relied almost exclusively on their pharmacy to determine their financial responsibility for a prescription. If the medication is not on the plan's formulary, the plan has prior authorization requirements or the cost is not affordable for the patient, therapy often is delayed or prescriptions go unfilled.

> ### NCPDP RTPB Standard
>
> *The Task Group found no data elements to be missing for a digital therapeutic and no information required by the RTPB Standard that would prevent the transactions from being used when the relevant product is a digital therapeutic complying with Use Case One.*

The RTPB Standard was developed to assist prescribers in selecting patient therapy with a greater understanding of the patient's specific prescription benefit and the cost of therapy to their patients or to the payers. Use of this information at the point of prescribing reduces requests prescribers receive from pharmacies asking them to prescribe a

less expensive medication, prescribe a medication that is on formulary or assist with a prior authorization request. Prescribers spend countless resources responding to these patient and pharmacy inquiries.

Finally, pharmacists may utilize the RTPB standard to access patient specific benefit information on alternative therapies available and costs, assisting them in answering requests from patients to understand their medication and cost options. Unlike the Formulary and Benefit Standard, the RTPB Standard is specific to the patient, and the provider obtains an immediate response to the inquiry. The RTPB transaction is used by the provider to request the processor return the following information:

NCPDP SCRIPT Standard

The Task Group found no data elements to be missing for a digital therapeutic and no information required by the any of the SCRIPT Standard transactions that would prevent the transactions from being used when the relevant product is a digital therapeutic complying with Use Case One.

- The eligibility of a specific patient according to appropriate plan parameters.
- Coverage information of the proposed product (medication, digital therapeutic, device or vaccine) and any preferred alternative products.
- The patient's financial responsibility when the product is covered or an explanation for why it is not covered or covered with restrictions.

3.4.2 TASK GROUP APPROACH TO ANALYSIS AND CONCLUSIONS

The RTPB standard uses components similar to those in the NCPDP SCRIPT Standard (Section 3.5), the NCPDP Telecommunication Standard Claim Billing Request and Response Transactions (Section 3.6) and the Formulary and Benefit Standard (Section 3.3). The task group reviewed the RTPB transactions and concluded that the standard will support digital therapeutics so long as the digital therapeutic complies with the NCPDP Product Identifier Standard (Section 3.2) and the NCPDP Billing Unit Standard (Section 3.1).

3.5   NCPDP SCRIPT STANDARD V2017071 TRANSACTIONS

Provider Selecting a Digital Therapeutic, Prescribing/Ordering and Electronically Transmitting the Prescription Order to a Pharmacy

NCPDP SCRIPT is a group of standard transactions created to facilitate the transfer of prescription data between pharmacies, prescribers and processor/PBMs. The current version of SCRIPT supports transactions used in sending new prescriptions, prescription changes, renewal requests, prescription fill status notifications and prescription cancellations. Enhancements have been added for drug utilization review/use (DUR/DUE) alerts and formulary information as well as transactions to relay patient medication history and for a facility to notify a pharmacy of resident patient information. Enhancements have been added to support electronic prior authorization (PA) functions as well as electronic transfer of prescriptions between pharmacies. The Digital Therapeutics Task Group has evaluated all of the SCRIPT transactions as to their suitability for supporting a digital therapeutic for a patient in the stated initial use case.

The task group found no data elements to be missing for a digital therapeutic and no information required by any of the SCRIPT the transactions that would prevent them from being used for a digital therapeutic product complying with the criteria of the initial use case.

3.5.1 PA TRANSACTIONS (PA INITIATION REQUEST/RESPONSE, PA REQUEST & RESPONSE, PA APPEAL REQUEST & RESPONSE, PA CANCEL REQUEST & RESPONSE)

The Prior Authorization (PA) transactions are exchanged in a real-time request and response mode. They provide a fully electronic means for determining whether health plan authorization is required for a particular product and patient.

PA transactions should not be confused with a NewRx transaction. The PA transactions are between the prescriber (system) and the payer (system) for payer authorization of therapy. A NewRx transaction is between the prescriber (system) and the pharmacy (system) for exchanging an electronic prescription order for that therapy. See Figure 1 in Section 2.3.2.

While the PA transactions are designed to be used during the electronic prescribing workflow when possible, they can also be used later – when a prescriber is informed a prescription sent to a pharmacy was determined to require prior authorization during claims processing. When integrated into the electronic prescribing process, use of the prior authorization transactions is said to be "prospective," whereas use after a pharmacy claim rejection is referred to as "retrospective."

The prior authorization information questions sent to the prescriber are presented in a consistent format, while enabling each payer to request the specific information it requires. While the NCPDP PA transactions enable a standard means for communicating each payer's set of questions to be answered by the prescriber before an authorization is granted, the PA transaction standard does not standardize the questions themselves nor does it specify how the questions are presented to the prescriber. That is, the questions themselves are not codified.

The prescriber system gathers the needed information from the prescriber and/or the patient's electronic medical record using coded references and returns it to the payer. The payer then notifies the prescriber of the determination.

The transactions involved include:
- PAInitiationRequest and PAInitiationResponse, where the prescriber system initiates the authorization process and the payer identifies the information required of the prescriber
- PARequest and PAResponse, which convey the prescriber-collected information to the payer and the payer's determination to the prescriber

3.5.2 NEWRX

New Prescription Transaction - This electronic transaction is a new prescription order from the prescriber to the pharmacy so that it can be dispensed to a patient.

The new prescription (NewRx) transaction is used to send a new prescription for a patient from a prescriber to a pharmacy. The new prescription transaction is originated by the prescriber's e-prescribing system or module.

The NewRx transaction contains a number of required fields that correspond to those required on a physical prescription. In addition, a number of optional or situational data fields are available as needed by the prescriber to convey information to the pharmacy. The optional/situational fields are much greater in number than what would be available on a physical prescription order and include benefit plan information and a number of patient demographic and clinical data fields.

Similarly, to a prescription for a specialty drug, when writing an electronic prescription for a digital therapeutic, additional patient information is sometimes sent via paper forms because this information is not currently part of the NewRx transaction. This is often the case when a third party or "hub" is performing specific services related to the patient such as benefit verification. Expanded patient contact and communication information becomes helpful. The task group determined this information could be sent in an ancillary transaction and the NewRx transaction can be used to transmit the order itself. The Digital Therapeutics Task Group contacted NCPDP Work Group 18 Specialty Pharmacy which has a task group focused on the development of a standard for specialty products with very similar needs. The Digital Therapeutics Task Group is working with Work Group 18 to ensure digital therapeutics business needs are included in the development of this new enrollment or intake standard. In the meantime, current paper processes should continue.

3.5.3 RxRENEWAL REQUEST/RESPONSE
The RxRenewal Request transaction is from the pharmacy to the prescriber requesting additional refills. The response transaction may be a new prescription (replace).

3.5.4 NEWRx REQUEST/RESPONSE DENIED
The NewRxRequest transaction is a request from a pharmacy to a prescriber for a new prescription order for the requested patient therapy. The ResponseDenied transaction is a denied response to the previously sent NewRxRequest. If the provider approves the NewRxRequest, a NewRx transaction is sent.

3.5.5 CANCELRx REQUEST/RESPONSE
The CancelRxRequest transaction is a request from the prescriber to the pharmacy to not fill a previously sent prescription. The response is from the pharmacy to the prescriber to acknowledge a cancel request. A CancelRxResponse is the response to a cancel request (CancelRxRequest).

3.5.6 RxCHANGE REQUEST/RESPONSE
Prescription Change Request Transaction (RxChangeRequest) is used when the pharmacy is asking for a change in the original prescription or validation of prescriber credentials. It is a request from a pharmacy to a prescriber asking for a change in a new prescription order or a "fillable" prescription order. It may also be utilized to request a prescriber to review the therapy requested and obtain a prior authorization from the payer for the prescription.

The RxChangeResponse is a response from a prescriber to a pharmacy for a prescription order change. It may also be used to send a response to a request for a prior authorization back to the pharmacy or prescriber credential validation.

3.5.7 RISK EVALUATION MITIGATION STRATEGY (REMS) INITIATION REQUEST/RESPONSE

The REMS Initiation Request transaction is a request to the REMS Administrator for the information required to submit a REMSRequest for a specified patient and therapeutic. The response transaction is a response from the REMS Administrator with the information required to submit a REMSRequest.

3.5.8 REMS REQUEST/RESPONSE

The REMSRequest transaction is a request to the REMS Administrator with information (answers to question set; clinical documents) to assist the REMS administrator in making a REMS determination (approved, denied, pended, etc.). The Response transaction is the administrator's response.

3.5.9 RxFILL

This transaction is sent to the prescriber or long term or post-acute care (LTPAC) organization from the pharmacy and indicates the status of the prescription's dispensing (dispensed, partially dispensed, not dispensed, transferred). It is the notification from a pharmacy to a prescriber when the prescription has been dispensed (picked up by patient), partially dispensed (e.g., partial amount of medication picked up by the patient), not dispensed (not picked up by patient) and medication returned to stock or transferred to another pharmacy. For LTPAC, it is the notification from a pharmacy to a LTPAC organization when the prescription has been dispensed (to be delivered to the specified facility or medication has been added to the profile for administration to the patient), partially dispensed (partial amount of medication to be delivered to the specified facility), not dispensed (medication will not be delivered to the specified facility) or transferred to another pharmacy.

3.5.10 RxFILL INDICATOR CHANGE

This transaction is sent by the prescriber to the pharmacy to indicate that the prescriber is changing the types of RxFill transactions that were previously requested. The prescriber may modify the fill status of transactions previously selected or cancel future RxFill transactions.

3.5.11 RxHISTORY REQUEST/RESPONSE

The RxHistoryRequest transaction is initiated by an entity requesting patient medication history from an entity that has the patient's medication history. Medication history is a list of medications that have been prescribed, dispensed, claimed or indicated to or by the patient. The Response transaction contains all the medication history data for the specific patient within the relevant time period.

3.5.12 GETMESSAGE

This transaction is used by the prescriber or pharmacy asking the mailbox if there are any transactions.

3.5.13 RESUPPLY

This transaction is a request from a LTPAC organization to a pharmacy to send an additional supply of medication for an existing order. An example use case is when a medication supply for a resident is running low (2-3 doses) and a new supply is needed from the pharmacy, the LTPAC organization needs a way to notify the pharmacy that an additional supply of the medication is needed.

It is not known if this message has applicability in digital therapeutics, but there is nothing about the message that would not allow its use.

3.5.14 RECERTIFICATION

This transaction is a notification from a facility, on behalf of a prescriber, to a pharmacy recertifying the continued administration of a medication order. An example use is when an existing medication order has been recertified by the prescriber for continued use. The transaction is only used in long term or post-acute care.

3.5.15 DRUG ADMINISTRATION

This transaction communicates drug administration events from a prescriber/care facility to the pharmacy or other entity. It is a notification from a prescriber/care facility to a pharmacy or other entity that a drug administration event has occurred - for example, a medication was suspended or administration was resumed.

It is not known if there is applicability in digital therapeutics.

3.5.16 RXTRANSFER REQUEST/RESPONSE/CONFIRM

The RxTransferRequest transaction is used when the pharmacy is asking for a transfer of one or more prescription orders for a specific patient to the requesting pharmacy. The Response transaction is the response to the RxTransferRequest which includes the prescription(s) being transferred (if accepted) or a rejection of the transfer request (if rejected). The Response is sent from the transferring pharmacy to the requesting pharmacy.

The Confirm transaction is used by the pharmacy receiving (originally requesting) the transfer to the transferring pharmacy to confirm the transfer prescription(s) have been received and the transfer is complete.

As previously stated, the Digital Therapeutics Task Group has evaluated all of the SCRIPT transactions as to their suitability for supporting a digital therapeutic for a patient in the stated initial use case.

3.5.17 MORE INFORMATION ON THE SCRIPT STANDARD TRANSACTIONS

NCPDP members can obtain the SCRIPT Standard Implementation Guide under the Standards Lookup Tool on the MyNCPDP™ website. Work Group 11 e-Prescribing and Related Transactions is responsible for the NCPDP SCRIPT Standard Implementation Guide and related documents below. Questions should be directed to WG11 e-Prescribing and Related Transactions.

The following documents are available to NCPDP members in support of SCRIPT Standard V2017071:

- Schema
- Implementation Guide
- XML Standard
- V2017071 SCRIPT Standard Examples Guide v14
- NCPDP SCRIPT 2017071 and 10.6 Comparison 20190311

3.6 NCPDP TELECOMMUNICATION STANDARD

Pharmacy Dispensing/Fulfilling and Billing for a Digital Therapeutic

The NCPDP Telecommunication Standard is a suite of transactions primarily designed for electronic communication between the pharmacy and the PBM or their designee ("processor"). The transactions often are routed through a switch and/or intermediary to perform value-added services for the pharmacy and/or processor. The Eligibility and Claims Billing Request and Response transactions were developed to facilitate the on-line, real-time electronic submission, adjudication and response of eligibility and claim transactions. The NCPDP Telecommunication Standard Implementation Guide supports prescription claim transactions between provider pharmacies and processors or between two processors (e.g., coordination of benefits).

A "provider" may be a retail pharmacy, mail order pharmacy, doctor's office, clinic, hospital, long-term care facility or any other entity which dispenses a medication or therapeutic product and submits claims for the product to a payer/processor for reimbursement. The "processor" (referred to as the health plan payer, processor or PBM) is often a third-party administrator of prescription drug programs on behalf of health plans. The processor also may be any other entity, which receives pharmacy benefit claims, makes a decision regarding the level of reimbursement to the provider and transmits a response to the provider.

Providers may choose to transmit certain prescription claims to an "intermediary." Intermediaries receive claims from switches or providers, perform editing/messaging and then either pass the claims to the appropriate switch or processor or return (reject) claims to the providers for correction. The reply from the processor also may pass to an intermediary for editing and messaging on its return to the provider.

The documents associated with the HIPAA named version of the Telecommunication Standard at the time of the publication of this paper are the *Version D.0 Implementation Guide dated August 2010 its associated Data Dictionary dated July 2007, the most recent External Code List and the Version D Editorial Document.*

Industry anticipates Telecommunication Standard Version F6 will be the next HIPAA-named version of the standard to be implemented by covered entities. The Task Group has reviewed Version F6 to identify if any changes between D.0. and F6 would make Version F6 of the Telecommunication Standard unusable for a digital therapeutic product. There are no changes incorporated between D.0 and F6 that create gaps for a digital therapeutic product.

NCPDP Telecommunications Standard

The Task Group found no data elements to be missing for a digital therapeutic and no information required by the any of the Telecommunication Standard transactions that would prevent the transactions from being used when the relevant product is a digital therapeutic complying with Use Case One.

The Telecommunication Standard contains the transactions or transaction sets in the following sections which have been analyzed by the Digital Therapeutics Task Group.

Note: The Task Group has not reviewed the reject codes and external codes used in the Telecommunication Standard. It is anticipated the same codes are applicable for digital therapeutics claims. However, if the trading partners determine additional reject codes or external codes are needed for digital therapeutics, they should submit a Data Element Request Form (DERF) to NCPDP requesting the additional codes. (See beginning of the document.)

3.6.1 ELIGIBILITY VERIFICATION REQUEST (E1) AND RESPONSE TRANSACTIONS

The Eligibility Verification (Request/Response) transactions are used by the originator (pharmacy) to request the processor/PBM/reporting entity verify the eligibility of a specific individual according to appropriate plan parameters. This transaction is used to request verification of a patient's or cardholder's status for a given benefit program. It is not specific to the covered items or drugs under that benefit. The transaction should be used identically whether the prescription order is for a physical or digital product.

3.6.2 CLAIMS BILLING TRANSACTIONS (B1)

The Claim Billing Request/Response transactions are for the pharmacy billing, processor/PBM adjudication and resulting claim amounts owed the pharmacy and copayment amount to be paid by the insured (patient). The Claim Billing Reversal and Rebill transactions are for the named purposes and work identically whether the product dispensed is a drug or digital therapeutic.

Claim billings may be for products dispensed (including drugs or digital therapeutics), DUR conflict resolution or professional services rendered by the pharmacy in conjunction with the digital therapeutic. Professional services may be correlated with a dispensing event or may be separate and unrelated to any particular dispensing event.

3.6.3 PRE-DETERMINATION OF BENEFITS TRANSACTIONS

These transactions assist pharmacists and their patients in determining if a given prescription would be covered under the patient's plan and provides information on patient responsibility costs. The patient can then determine if they want to proceed with filling the order. Pharmacies use this transaction to determine if the product is covered before submitting a claim and fulfilling the order.

3.6.4 SERVICE BILLING TRANSACTIONS

These transactions are not widely adopted by the industry at the time of publication. If a Claim Billing (B1) transaction needs to be sent for a professional service performed, the sender should use a Prescription Service Reference Number (field 455-EM) of Service Billing (02) rather than Rx Billing (01) in the Claim Segment. The Claim Segment also allows for the use of Procedure Codes in the Product/Service ID field 407-D7 and Procedure Modifier Codes in field 857-ER in the Claim Segment.

3.6.5 PRIOR AUTHORIZATION INQUIRY/REQUEST/RESPONSE TRANSACTIONS

These transactions are also between a pharmacy and a processor/PBM and allow a processor/PBM to authorize, authorize and immediately adjudicate, defer or pend for review the product or service. These are not the PA Transactions discussed in Section 3.3.1 that should occur between the prescriber and the processor/PBM *prior* to a prescription order. Those transactions are preferred over these transactions by all parties as they allow the prescriber and the patient to determine coverage and cost prior to sending the prescription. If the patient has to wait for authorization after the prescription is at the pharmacy, studies show patients frequently never pick up their prescription and, therefore, do not receive the therapy.

3.6.6 INFORMATION REPORTING/REBILL/REVERSAL TRANSACTIONS

Information Reporting Request/Response/Reversal transactions allow processors or authorized reporting entities to collect information about clinical and professional services most likely related to a prior

dispensing event. The most common example of the use of this transaction is for information reporting related to Medicare Part D. The Pricing Segment is situational for an Information Reporting Request. The Pricing Segment only supports the field Patient Paid Amount Submitted (433-DX) that is used in Medicare Part D payer-to-payer facilitation. Otherwise, the Pricing Segment is not used.

NCPDP members can obtain the Telecommunication Standard Implementation Guide under the Standards Lookup Tool on the MyNCPDP™ website. Work Group 1 Telecommunication is responsible for the NCPDP Telecommunications Standard Implementation Guide and related documents. Questions should be directed to WG1 Telecommunication.

The following documents are available to NCPDP members in support of the HIPAA named Telecommunication Standard Version D.0. Similar documents are or will be available for the next HIPAA named version:

- Telecommunication Standard Implementation Guide (Last Revised: August 2010)
- July 2007 Data Dictionary (Only this publication of the Data Dictionary is applicable)
- July 2007 External Code Lists and higher publications
- Version D Editorial Document
- D.0 Matrices
- Emergency Telecommunication ECL Value Addendum
- Appendix A of the Telecommunication Standard Implementation Guide provides a history of version changes for the standard.

3.7   BENEFIT INTEGRATION STANDARD

Patient's Health Plan and PBM Share Information on Patient Deductibles and Benefit Maximums to Manage Patient's Benefit Costs.

The Benefit Integration Standard is intended to facilitate the integration and exchange of accumulators between benefit administrators to administer integrated benefits in an efficient manner. The accumulator data is exchanged between trading partners in agreed upon intervals. The exchange is either in batch or real time. In some situations, the trading partners each hold the accumulators (Dual Book of Records); in other situations, there is one trading partner that maintains the accumulator data (Single Book of Records). The standard is capable of transporting accumulator data for various benefit types, across all health care providers such as pharmacy, major medical, dental, behavioral health and lab. The NCPDP *Benefit Integration Standard Implementation Guide* allows for fixed length as well as XML transactions. The implementation guide provides both example transactions and FAQs.

3.7.1   REAL-TIME ACCUMULATOR INQUIRY BY PBM

Benefit integration solutions that reduce the time lag between the accumulation event (e.g., claim transaction) and the posting of the calculated amounts provides improved pricing accuracy and better payer/patient/member experience. Both the Dual Book and Single Book models provide a methodology for exchange of accumulators in real-time. In the Single Book of Records benefit integration exchange, the benefit partners query accumulator balances from the custodian and use the balances in their adjudication process (inquiry phase). Once adjudication is completed, the partners communicate the

changes to the accumulators as a result of adjudication to the custodian so the custodian can update the Single Book of Record (post update/change phase).

3.7.2 APPLICABILITY FOR DIGITAL THERAPEUTIC PRODUCTS

The Digital Therapeutics Task Group enlisted the assistance of NCPDP's WG1 Benefit integration Task Group co-leads to identify possible gaps using the Benefit Integration Standard for updating a patient's accumulators with data from the dispensing of a digital therapeutic.

It was determined that, because the Telecommunication Standard Claim Billing Request and Response transactions can be used for a digital therapeutic, all the data elements needed for updating patient accumulators using the Benefit Integration Standard data elements are available.

> **NCPDP Benefit Integration Standard**
>
> *The Task Group found no data elements to be missing for a digital therapeutic and no information required by the Benefit Integration Standard that would prevent the standard being used to send benefit related information when the relevant product is a digital therapeutic complying with Use Case One.*

3.7.3 FUTURE BENEFIT DESIGN CONSIDERATIONS

The two task groups discussed the possibility that future benefit designs could have separate deductibles, maximum out-of-pocket costs and maximum annual or lifetime benefits for digital therapeutics. The two task groups will address the impact of a new business need for managing benefit designs with separate accumulators at a future date.

3.8   X12N 835 HEALTH CARE CLAIM PAYMENT/ADVICE

Payer Sending Electronic Remittance Information on Claims Payment to a Pharmacy

3.8.1 INTRODUCTION TO 835 PAYMENT/ADVICE TRANSACTION SET

A pharmacy claim is processed in real time using the NCPDP Telecommunication Standard. The pharmacy receives information from the PBM in real time notifying the pharmacy of the amount of copayment to collect from the patient and the amount the PBM will reimburse the pharmacy.

However, the pharmacy payment does not occur in real time. Payment to the pharmacy is made later, usually electronically, accompanied by an X12 835 Payment/Advice describing all the claim reimbursements corresponding with the electronic payment. This X12 transaction is used for payers to pay claims to providers regardless of whether the benefit is part of the pharmacy benefit or the medical benefit. All payers use this transaction. This transaction can be used to make a payment, send an Explanation of Benefits (EOB) remittance advice or make a payment and send an EOB remittance advice from a payer to a pharmacy either directly or via a financial institution.

The Digital Therapeutics Task Group enlisted the assistance of NCPDP's X12 Liaison to identify possible payment/remittance gaps using an X12 835 transaction. It was determined that so long as the NCPDP Telecommunication Standard Claim Billing transaction is void of gaps (which it is for Use Case One), the X12 835 will work for a digital therapeutic product.

4.   FREQUENTLY ASKED QUESTIONS

This section of the guidance document will be updated as questions are received, reviewed and answers approved by the Council. Updates will occur not more frequently than quarterly.

1. Our organization has a new digital therapeutic. How can we ensure the NCPDP Telecommunication Standard and SCRIPT Standard transactions will support our product?

    Response: Refer to Section 2.3.2 "Pharmacy Fulfillment and Billing of Prescription Digital Therapeutic (Initial Use Case)," Section 3.1 NCPDP Billing Unit Standard and Section 3.2 NCPDP Product Identifiers Standard. If your new digital therapeutic complies with the requirements outlined in these sections, the standards noted in this document will support your product. If you have any concerns or are unclear, contact NCPDP at 480-477-1000 or via email at ncpdp@ncpdp.org.

2. Does my product need a product identifier code to be used in NCPDP transactions?

    Response: The NCPDP Standards require a product identifier. NDC, UPC, NHRIC or GTIN identifiers can be reformatted per the NCPDP Product Identifier Standard. Please refer to Section 3.2 Product Identifier Standard.

3. For the initial use case, can a physician bill for digital therapeutics using the NCPDP Telecommunication Standard Claim Billing transaction if they are the dispenser?

    Response: If a physician has been enabled to bill the patient's prescription benefit using the Telecommunication Standard for dispensing medications from their office, then the same application used may be used for billing a digital therapeutic. The physician should consult the organization providing the physician dispensing and billing service for details.

5.   APPENDIX A

The Summary Information Model illustrates the types of information contained in the Formulary and Benefit Standard Version 53 files.
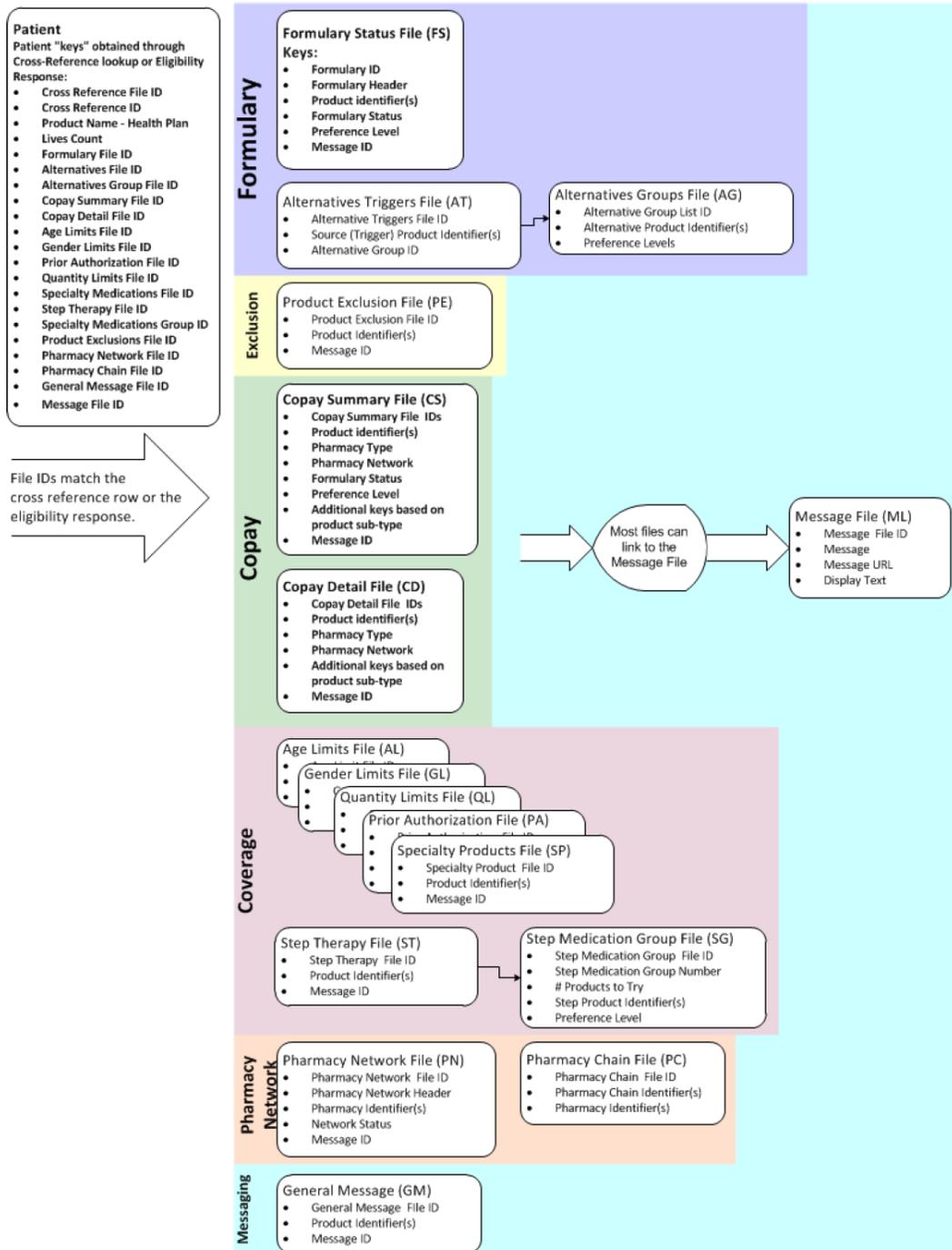

Figure 2: Formulary and Benefit Summary Information Model

6. APPENDIX B – DOCUMENT REVISIONS

6.1 VERSION 1.0

Original Publication

6.2 VERSION 1.1

- Updated list in NCPDP Standards on section 1.2
- Updated figure 1 in section 2.3.2
- Updated list in NCPDP Standards Potentially Utilized by the Initial Use Case section 2.3.2.1
- Updated list in Standards Review section 2.3.3
- Updated section 3 Standards Review
- Added section 3.3 for Formulary and Benefit Standard
- Added section 3.4 for RTPB Standard
- Updated section 3.6 NCPDP Telecommunication Standard
- Added section 3.7 for Benefit Integration Standard
- Added section 3.8 for X12N 835 Health Care Claim Payment/Advice
- Added Appendix A