

# Facilitating Access to Specialty Products – An NCPDP Review and Recommendations

*Version 10*

May 2022



This paper offers recommendations to manufacturers, prescribers, payers and pharmacies regarding the information related to hub services and limited distribution products.

## Facilitating Access to Specialty Products – An NCPDP Review and Recommendations

Version 10

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## 1. PURPOSE

The WG18 Facilitating Access to Specialty Products Task Group developed this paper to provide recommendations to manufacturers, prescribers, payers and pharmacies regarding information about limited distribution products and hub services available at the time of prescribing. These recommendations address the current need for patients and prescribers to know what services are available and assist with patient access to therapy.

Feedback from the industry indicated many times patients, providers and payers are unaware of which pharmacy providers have access to limited distribution medications being prescribed as well as the patient services available through manufacturer hubs to lower the cost of therapy for those products.

Almost two out of three people (63%) with chronic conditions said they would opt into pharma services, according to the survey by Human Care Systems. However, the results revealed 80% were unaware of pharma patient support programs.<sup>1</sup>

The intent is for manufacturers of the medications to make the information accessible to patients, providers and payers via a standardized platform or format.

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<sup>1</sup> <https://www.fiercepharma.com/marketing/majority-patents-want-pharma-support-services-but-awareness-programs-still-low-survey>

## **2. SCOPE**

This paper addresses the availability of information about specialty products with limited distribution networks and/or designated hub/patient services. It is not intended to address open access specialty products.

### 3. DEFINITIONS

- **Benefit Investigation:** Process that enables stakeholders to determine benefit design, coverage requirements and billing recommendations. This would include formulary restrictions as well as patient cost share.
- **Copay Cards:** Copay cards are manufacturer sponsored cards that help patients offset the cost of product. Certain criteria must be met to be eligible for a copay card.
- **Drug Compendia:** The source of drug information utilized in various healthcare processes such as prescription claims adjudication, drug coverage, prescription claims pricing, e-prescribing, formulary management, and others. Compendia also provide clinical information about drug products for use in coverage decisions and clinical decision support.
- **Foundational Support:** Non-profit or manufacturer sponsored program that provides financial assistance for patients that meet criteria for a specific product or disease state.
- **Free Goods/Patient Assistance Program:** Free Goods or Patient Assistance programs are manufacturer sponsored programs that assist patients obtain free product after meeting certain criteria.
- **Hub Services:** Hub services are manufacturer sponsored programs that assist patients and prescribers in the areas of access, affordability and adherence services providing efficient distribution of medication improving patient compliance. Hub services can also be known as Patient Services or Patient Services Support.
- **Limited Distribution Drug:** A product for which a manufacturer contracts with one or more select specialty pharmacies to dispense.
- **Patient:** An individual who has received, is receiving or intends to receive healthcare services. (Healthcare services as defined by federal and state regulations.) Can be a cardholder, subscriber, member, beneficiary or dependent.
- **Payer:** An entity that is either financially responsible or remits financial reimbursement of goods and/or services. A “PAYER” is often a third-party administrator of prescription drug programs on behalf of insurers. The payer also may be an insurer, a governmental program or any other entity which receives prescription drug claims.
- **Pharmaceutical Manufacturer:** An entity that develops, manages, manufactures and markets pharmaceuticals licensed for use as products. It may be involved in database/disease state management. It may develop, produce and market devices licensed for use. The pharmaceutical manufacturer is responsible for the Risk Evaluation and Mitigation Strategy (REMS) and for contracting with the REMS Administrator.
- **Pharmacy Benefit Manager (PBM):** Typically, a third-party administrator of prescription drug programs, PBMs can assist a plan sponsor in achieving the most effective utilization of prescription drug expenditures through benefit design, formulary management, rebate contracting, retrospective Drug Utilization Review (DUR), prospective DUR, network administration and disease management. The PBM may also be a payer/processor or other entity that receives prescription drug claims, makes a decision regarding the level of reimbursement and sends the appropriate message or reject code back to the pharmacy/provider for action.

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- **Prescriber:** A licensed entity that prescribes prescription drugs and provides professional medical services, such as clinical services respective to the prescribing function. The entity may be a clinic or independent prescriber, hospital or care facility.
- **Quick Start Program:** Program sponsored by a manufacturer to allow patient to start therapy immediately with a limited supply while reimbursement challenges are being addressed.
- **Specialty Pharmacy:** A specialty pharmacy is a state-licensed pharmacy that solely or largely provides only products for people with serious health conditions requiring complex therapies. These may include conditions such as cancer, hepatitis C, rheumatoid arthritis, HIV/AIDS, multiple sclerosis, cystic fibrosis, organ transplantation, human growth hormone deficiencies and hemophilia and other bleeding disorders.
- **Technology Vendor:** An entity that provides software and perhaps hardware to pharmacies or prescribers that enables electronic processing of business functions such as electronic prescribing, electronic medical records, appointments and scheduling and billing functions.



## 4. ACTORS: ROLES AND RESPONSIBILITIES

- **Hub Services:** Hub services assist patients and prescribers in the areas of access (e.g., cost, free goods), affordability and adherence services. Hub services work with payers and PBMs to understand the patient’s coverage, price and distribution options. Hubs provide the links between the manufacturer, prescriber, pharmacy and patient to facilitate the dispensing of the product.
- **Non-Specialty pharmacy (retail):** Retail pharmacies have the challenge of access, product knowledge and inventory when it comes to specialty and/or limited distribution products.
- **Patients:** At the time of prescribing, the patient may not have insight into the pharmacy benefit coverage available to them (e.g., copay, prior authorization requirements), their out-of-pocket cost if uninsured or the distribution process of the product. When the patient goes to obtain the product at their preferred pharmacy, they may not be able to have it filled due to a prior authorization need, the high cost or the limited product availability through a specific specialty pharmacy.
- **Payers / PBMs:** Payers or PBMs enter into contracts with pharmaceutical manufacturers regarding the coverage, price and distribution of product. They evaluate new products and determine formulary/coverage status.
- **Pharmaceutical Manufacturer:** The pharmaceutical manufacturer works with a hub program and owns the service offerings around access, affordability and adherence services. The pharmaceutical manufacturer has a direct relationship with the specialty pharmacies that are chosen to dispense the limited distribution or specialty product.
- **Prescriber:** At the time of prescribing, a prescriber may not have insight into their patient’s coverage requirements, out-of-pocket cost or the distribution process of the product. A prescriber, also, may not know what service offering the manufacturer has set up through a hub program.
- **Specialty pharmacy:** Specialty pharmacies dispense pharmaceutical therapies that are higher in cost and are used to treat rare and more complex disease states. In doing so, they may fill the role of disease management support including patient support with utilization management, adherence and providing supportive care and ancillary supplies (e.g., companion products, syringes, needles.)
- **System vendors:** System/technology vendors provide the platform for the communication of electronic health information between healthcare providers including physicians, hubs and pharmacies. Many can provide interfaces to run trading partner agreed upon customized data sets and/or transactions needed for efficient exchange of health-related information.

## 5. USE CASES

### **5.1 USE CASE 1: HUB/PATIENT SERVICES SUPPORT**

Many times, prescribers and/or patients are unaware of hub/patient services. These services can include reimbursement assistance (benefit identification and/or prior authorization support), financial/copy assistance, patient education, adherence service and drug delivery/administration support. This lack of knowledge may cause a patient to choose not to fill a prescription or drive the prescriber to choose a less desirable therapeutic option for that patient. Cost or barriers to coverage may be identified through a benefit inquiry and adherence services can assist with keeping a patient on therapy. Prescribers who do not receive prescription fill status messages may not realize that a patient did not fill a medication leading to lack of adherence knowledge.

In the current landscape, prescribers and patients are dependent on prescriber portals, sales support, marketing/promotional information or online research to know if a product has hub/patient services. These services are provided by the manufacturer and/or a separate entity on behalf of the manufacturer. The manufacturer is often the owner of the hub phone number, fax number and prescriber portal URL.

The recommended solution would create awareness about hub/patient services at the point of prescribing allowing the patient and prescriber to discuss available options leading to enhanced patient adherence.

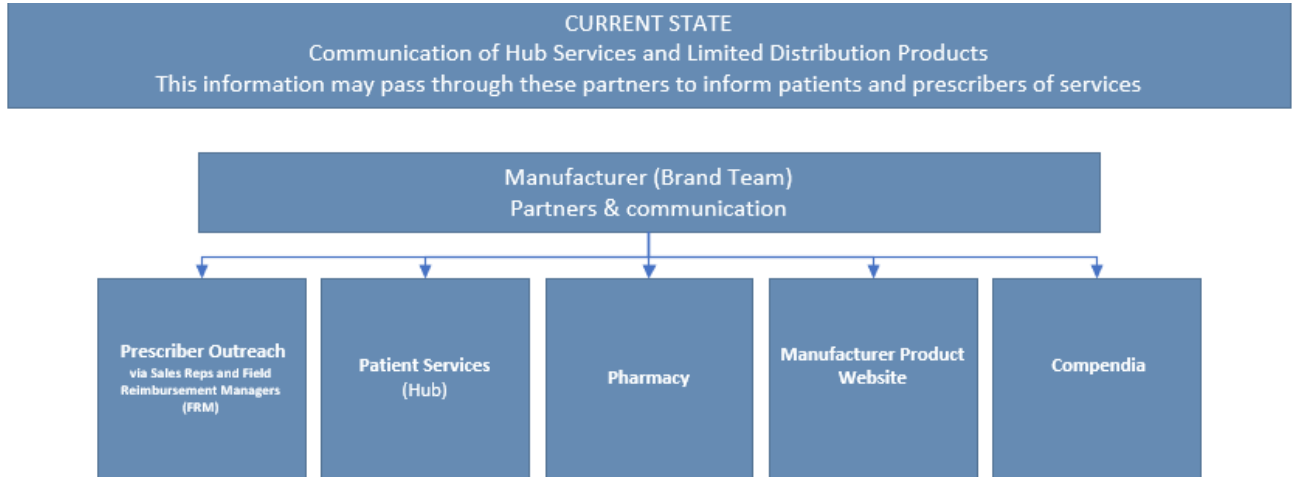
### **5.2 USE CASE 2: LIMITED DISTRIBUTION**

For some specialty products, a manufacturer may choose to use a limited distribution specialty pharmacy network. The specialty pharmacies in this network are selected based on their expertise and ability to offer optimal patient outcomes related to patient education, adherence, adverse event reporting and management. This limited distribution specialty pharmacy network allows the manufacturer to work with a small number of specialty pharmacies to carry the product. This may be due to the small patient population the product serves or the complexity of the drug (e.g., cold chain). Many times, the prescribers, patients and payers or PBMs are unaware when a specialty product is available only through a limited distribution network. This lack of visibility can create confusion with prescribers, patients and payers or PBMs regarding who can distribute the product. Delays in care may also occur if the designated pharmacy is not contracted with the patient's payer or PBM.

The recommended solution is to create awareness about limited distribution products at the point of prescribing allowing the patient and the prescriber to discuss available options leading to enhanced patient adherence. Making the information available to payers or PBMs would allow them to initiate the contracting process, reducing or eliminating delays in access to care for patients.

## 6. CURRENT STATE: ENTITY RELATIONSHIP DIAGRAM

This diagram is an illustrative example of how information about Hub Services and Limited Distribution Products is currently shared. Further in the document is another diagram that reflects proposed changes to the flow.



## 7. RECOMMENDATIONS

The recommendation is to have a frequently maintained, accurate central repository, accessible to all patients, providers and patients, for the sharing of information related to limited distribution products and hub services. This approach addresses a specific industry need where the information currently available without a central repository is confusing, incomplete and difficult to access.

The following are the benefits and challenges related to a central repository.

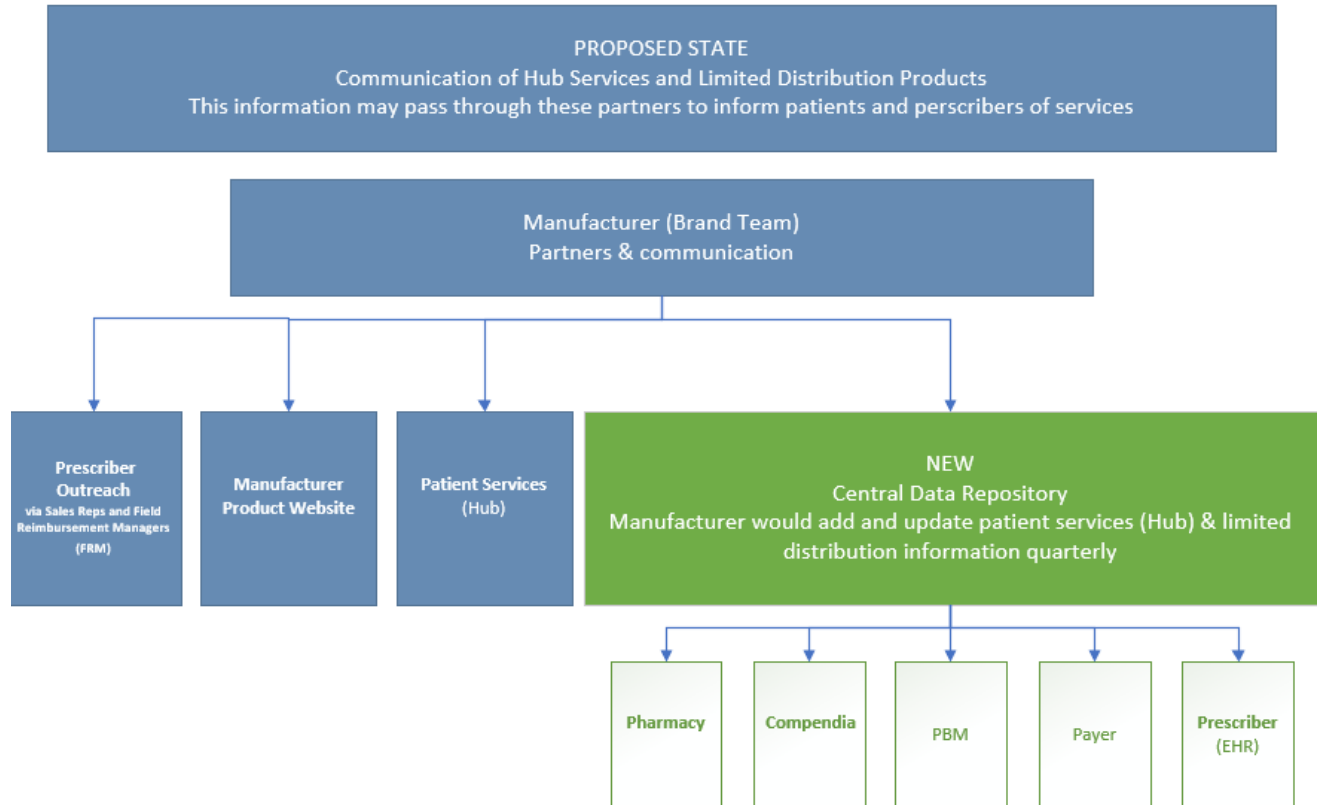
### Benefits:

- All patients, providers and payers have access to the same, up to date information; information is available from one place.
- Instant access to information.
- Less investigation and follow up for prescribers and pharmacies.
- Patients have faster access to their prescription(s).
- Addresses an industry need.
- Complements what is available in the NCPDP Real-Time Prescription Benefit transactions and potentially a consumer facing transaction.
- Decrease in turnaround for the manufacturer time to first fill.

### Challenges:

- Requires an entity to host the central repository.
- Data population and timing; requires frequent updates to remain relevant.
- Consistent ownership of data management and frequent changes.
- Unfamiliarity with the pharmacy or hub products and services.
- Unknown financial model for developing or maintaining central repository

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The central repository would be based on product name and would at a minimum provide the following:

- I. Limited Distribution Products
  - a. Product
    - i. Brand/generic/biosimilars
    - ii. Product Identifier
      1. NDC
      2. RxNorm
      3. HCPCS
    - iii. Manufacturer Name
    - iv. Distributor/Wholesaler Name (list all)
    - v. Limited Network Pharmacy Info
      1. Pharmacy Name
      2. Address
      3. Phone/Fax
      4. Website
      5. NPI/NCPDP ID
- II. Hub Support
  - a. Program Name
    - i. Phone Number
    - ii. Fax

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- iii. Website
  - 1. Enrollment Form
  - 2. Enrollment Transaction
- b. Services Offered
  - i. Reimbursement Support (Benefit Investigation, Prior Authorization, Appeal)
  - ii. Quick Start/Bridge Supply
  - iii. Copay Cards
  - iv. Foundational Support
  - v. Patient Assistance Program (PAP) – free product
  - vi. Drug Administration (Nursing Services)
  - vii. Adherence/Patient Education
- III. Maintenance
  - a. Timing of Updates
    - i. Quarterly
      - 1. Last Updated Date
  - b. Responsible Party

The provider of the central repository will be responsible for developing, implementing and maintaining a data management process that ensures information is routinely updated.

## 8. CONCLUSION

Specialty pharmacy and hub services are an integral part of the patient journey. A patient is better served by prescribers that can deliver specialized care, monitor adherence and drive positive outcomes for their chronic illnesses. The challenge is to ensure that patients, providers and payers have current and accurate information. Knowledge regarding hub services and limited distribution products remains an unfulfilled need of the industry.

Offering information in a central repository accessible by patient care providers will facilitate timely access to specialty products and hub services. There is an opportunity for interested parties to create and manage this central repository.

NCPDP looks forward to working with industry partners to develop standard requirements and guidance for the use of the repository.

## 9. REFERENCE

### [NCPDP Specialty Pharmacy Benefit Coverage Identification White Paper](#)

*This document highlights the current challenges experienced by providers, dispensers and organizations in being able to timely and accurately identify the appropriate benefit coverage (medical or pharmacy benefit) for a specific medication being prescribed, as well as potential out-of-pocket costs to the patient, at the time of care.*

### [HL7® FHIR® Specialty Medication Enrollment Implementation Guide](#)

*The implementation guide describes the exchange of data (patient demographic and coverage, prescription and clinical) for dispensing specialty medications by pharmacies as well as facilitating enrollment of patients in programs offered by third parties such as, but not limited to, hub vendors and pharmaceutical manufacturers. This document represents the collaborative efforts of NCPDP and HL7® to be co-branded between HL7® and NCPDP.*



## 10. APPENDIX A – HISTORY OF CHANGES

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