RISK EVALUATION & MITIGATION STRATEGIES (REMS)

REFERENCE GUIDE FOR TELECOMMUNICATION STANDARD VERSION 5.1

VERSION 1.Ø

This document provides guidelines for using the NCPDP Telecommunication Standard for Risk Evaluation and Mitigation Strategy implementations and to ensure a consistent implementation of the standard.

August 2Ø1Ø

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REMS Reference Guide

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1. INTRODUCTION

This NCPDP *REMS Reference Guide* is intended to meet two needs within the pharmaceutical industry: (1.) to provide practical guidelines for software developers throughout the industry as they begin REMS Implementation using the NCPDP v5.1 Telecommunication Standard and (2.) to ensure a consistent implementation of the standard throughout the industry.

The Food and Drug Administration Amendments Act (FDAAA) of 2ØØ7 (Public Law 11Ø-85) enables the Food and Drug Administration (FDA) to require a Risk Evaluation and Mitigation Strategies (REMS) from a pharmaceutical manufacturer if the FDA determines that a REMS is necessary to ensure the benefits of a drug outweigh the risks associated with the drug. Drugs currently approved by the FDA, including those with existing RiskMap programs, are also subject to a retrospective FDA review to determine if REMS is necessary. This authority extends to any manufacturer submitting a new drug application (NDA), abbreviated new drug application (ANDA), and biologics license application (BLA).

A REMS includes a timetable for the submission of assessments of the REMS. A REMS may also include any of the following:

- A Medication Guide (MedGuide)
- A Patient Package Insert (PPI)
- A Communication Plan
- Certain "Elements to Assure Safe Use" (ETASU)

The ETASU may include any combination of the following requirements:

- Health care providers who prescribe the drug have particular training or experience, or are specially certified.
- Pharmacies, practitioners, or health care settings that dispense the drug are specially certified.
- The drug is dispensed to patients only in certain health care settings.
- The drug is dispensed to patients with evidence of safe use conditions, such as laboratory test results.
- Each patient using the drug is subject to certain monitoring.
- Each patient using the drug is enrolled in a registry.

During the drug approval process, the FDA will determine whether a REMS will be required. If the FDA finds that a REMS is necessary to ensure that the benefits of the drug or biological product outweigh the risks of the product, and FDA notifies the sponsor of the application to submit a proposed REMS and the REMS will be approved with the drug/biological (innovator) product is approved/licensed.

The (FDAAA) Act also contains REMS requirements for drug and biological products approved before the effective date of Title IX, subtitle A. This allows for new REMS requirements for drugs that have been on the market for some time. In this case, either an innovator or pioneer and generic forms of the same drug may exist. The FDA requires innovator and generic drugs use a shared REMS if the REMS includes ETASU and the innovator and generic manufacturers must work together. A waiver of this requirement can be made for the generic applicant if evidence is brought forth that:

- The burden of a single system outweighs benefits; or
- An aspect of ETASU is intellectual property.

The FDA is in the process of drafting guidance for the first "Class REMS" for opioids. This opioid Class REMS is expected to be applied to all current and proposed extended-release opioids and methadone, which are dispensed via retail pharmacies. It is assumed a "Class REMS" will have the same features as cases when both innovator and generic forms of the same drug exist.

The currently approved REMS programs vary in levels of complexity. Most require only a Med Guide and Communication Plan, but some require ETASU. The large majority of existing REMS programs are for drugs dispensed through specialty pharmacy, clinics, and hospitals but as REMS become more common they will ultimately have a greater impact on retail-based products.

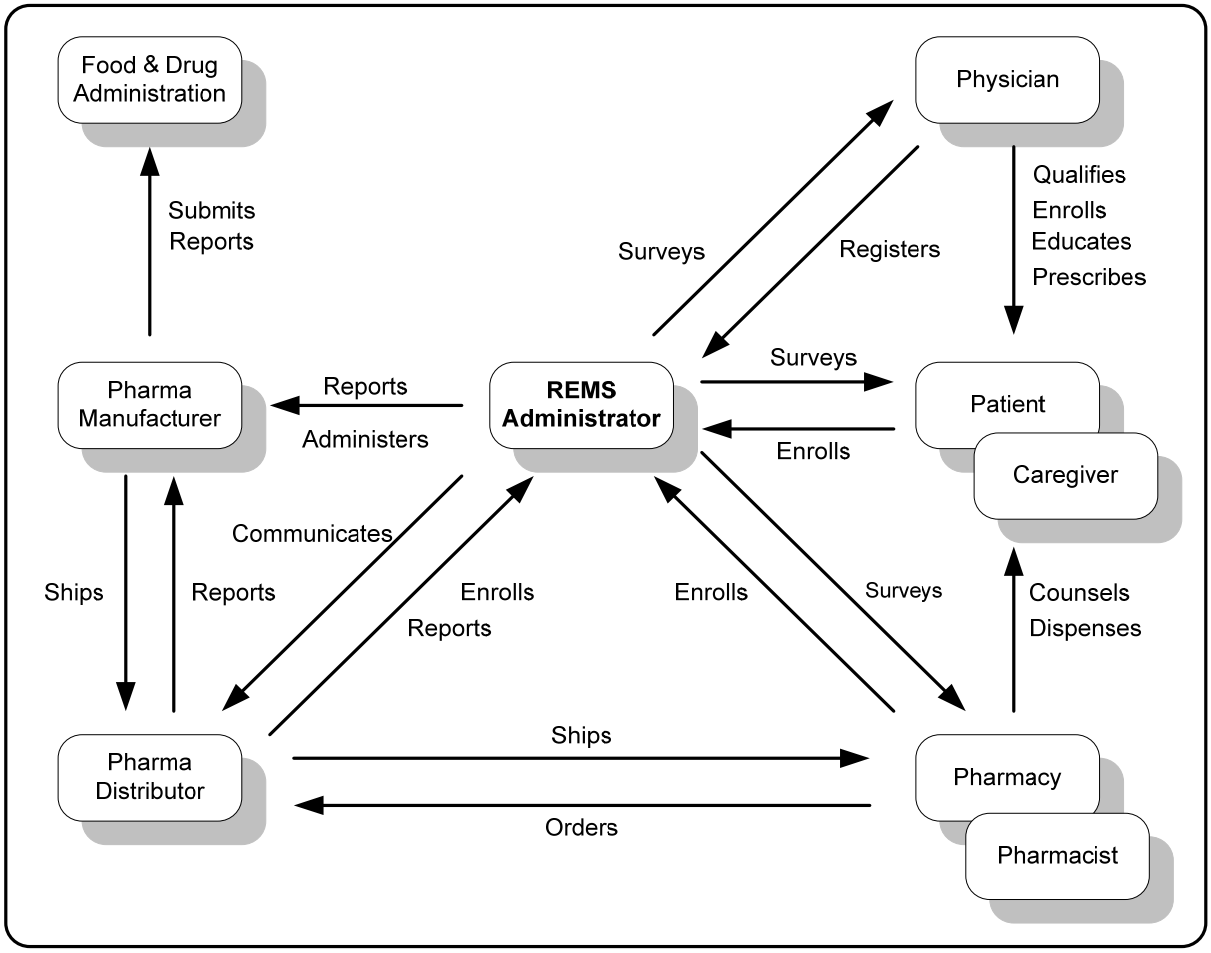
Ensuring REMS compliance for products commonly found in a retail or community pharmacy setting presents pharmacies and manufacturers with several logistic challenges. This guide directly addresses these types of REMS and challenges with the goal of integrating these processes into the retail/community pharmacist's workflow and minimizing burden as much as possible.

The primary implication of REMS for the industry is twofold. First, REMS with ETASU may require the pharmacist to verify prescriber, patient, and/or pharmacy enrollment in a registry and, in some cases, verify or check certain information, such as lab results. Second, all REMS, including those without ETASU, must fulfill FDA-approved reporting requirements. All REMS are subject to FDA audits which are based on detailed data capture and reporting elements. Each REMS program must also include a program assessment schedule that examines the program's effectiveness on intervals approved by the FDA as part of the overall REMS program. The results of these assessments are submitted to the FDA as part of the ongoing evaluation of REMS program effectiveness. Failure to comply with REMS requirements can result in fines and potentially lead to removal of a drug from the market.

This guide describes how the Telecommunication Standard (Version 5.1), and specifically the Billing transaction is to be used to automate the preceding REMS requirements. This automation includes a REMS verification transaction and data capture to fulfill reporting requirements.

If you have any questions regarding the availability or content of the NCPDP *REMS Reference Guide*, see www.ncpdp.org, or contact the Council office at (48Ø) 477-1ØØØ or via e-mail at ncpdp@ncpdp.org.

1.1 SAMPLE REMS MODEL FOR DRUGS DISPENSED BY OUTPATIENT PHARMACIES



1.2 DOCUMENT SCOPE

This document contains the specification and implementation guide. Users of this document should consult the NCPDP documents listed below for further information and clarification.

TELECOMMUNICATION STANDARD IMPLEMENTATION GUIDE

Specifies transmission formats for claim submissions and responses. Refer to *NCPDP Telecommunication Standard Implementation Guide Version 5.1*.

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DATA DICTIONARY

Full reference to all data elements with definition, sizes, and values used in NCPDP documents.

EXTERNAL CODE LIST

Full reference to all values used in NCPDP documents.

STANDARDS MATRIX

This document contains charts that list the Standards and Implementation Guides versions approved or under consideration by NCPDP, with reference to the Data Dictionary and External Code List documents appropriate for use.

NCPDP produces a comprehensive *Data Dictionary* for all approved standards. The NCPDP *Data Dictionary* document specifies valid field values and definitions for all elements in this standard as well as other NCPDP approved standards. The NCPDP *Data Dictionary* has been modified to remove some data elements contained in the previous releases of the standard that were considered impractical and unnecessary for the new standard. Data elements that were not brought forward are noted in the appendix "*Data Dictionary Field Deletions*" section of this document.

These documents are available to NCPDP members in the "Members" section of the website at www.ncpdp.org. Non-members may purchase the documents; please see www.ncpdp.org or contact the NCPDP office at 48Ø-477-1ØØØ, or via Internet e-mail at ncpdp@ncpdp.org.

2. BACKGROUND

On September 27, 2ØØ7, the President signed into law the Food and Drug Administration Amendments Act of 2ØØ7 (FDAAA). This legislation, with the intent to continue the FDA's oversight of drug commercialization, went into effect in March, 2ØØ8. Included in these amendments is the authority for the FDA to require entities submitting new drug applications (NDAs), abbreviated new drug applications (ANDAs), and biologics license applications (BLAs) to also submit a proposed Risk Evaluation and Mitigation Strategy (REMS) if the FDA determines that such a strategy is necessary to ensure that the benefits of the drug outweigh the risks of the drug. Drugs currently licensed by the FDA, including those with existing RiskMap programs, are also subject to a retrospective FDA review to determine if REMS is necessary.

Once it is determined that a REMS is necessary, the application/license holder must submit a proposed REMS within a reasonable time as required by the FDA. It is the responsibility of the holder to design the REMS program and submit it to the FDA for approval. REMS programs typically consist of one or more of the following components:

- Medication guide
- Patient registry
- Physician registry
- Dispensing pharmacy/hospital/clinic certification
- Patient monitoring
- Controlled distribution

All REMS are subject to FDA audits which are based on detailed data capture and reporting elements. Each REMS program must also include a program assessment schedule that examines the program's effectiveness on intervals approved by the FDA as part of the overall REMS program. The results of these assessments are submitted to the FDA as part of the ongoing evaluation of REMS program effectiveness. Failure to comply with REMS requirements can result in fines and potentially lead to removal of a drug from the market.

3. BUSINESS ENVIRONMENT

3.1 OBJECTIVES

The objective of the NCPDP *REMS Reference Guide for Telecommunication Standard* (Version 5.1) is to support a description of how a retail/community or other outpatient pharmacy can use Version 5.1 of the standard to support the registration verification, clinical appropriateness editing, counseling documentation, and/or dispensing activity reporting requirements for products with a REMS requiring "elements to assure safe use" (ETASU). The implementation describes the following scenarios

- Registration Verification via 5.1 Billing Transaction
- Counseling Documentation via 5.1 Billing Transaction

3.2 PARTICIPANTS

The NCPDP *Telecommunication Standard Implementation Guide* (Version 5.1) supports outpatient or ambulatory patient prescription billing transactions, services, and reporting between industry participants.

Providers, Switches, and REMS Administrators

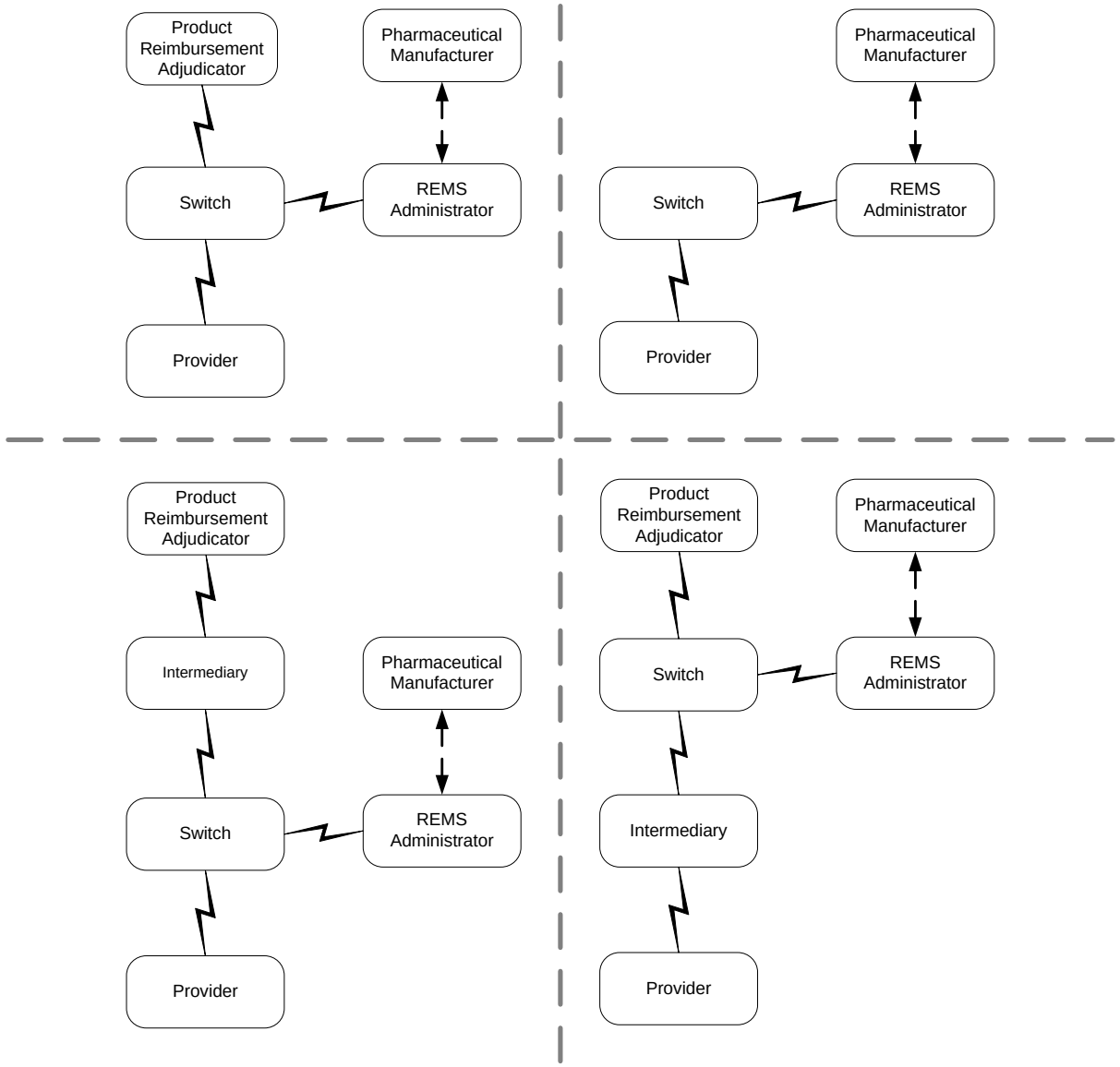
The communication between Providers and Adjudicators (Processors) is two-way and the record layout for the transmitted Rx Billing or Service Billing requests and the response to these request transactions are defined by the appropriate version of the Telecommunication Standard. (Note the value of Prescription/Service Reference Qualifier (455-EM) differentiates Rx versus Service Billing.)

- Rx Billing – Version 5.1
- Service Billing – Version 5.1

This reference guide describes how industry participants can implement Registration Verification, Clinical Appropriateness, and Data Reporting requirements using NCPDP Telecommunication Standard Version 5.1.

Registration Verification via 5.1 Rx Billing Transaction

The diagram below illustrates the typical business environments in which the NCPDP *Telecommunication Standard Implementation Guide* (Version 5.1) is employed between pharmacy providers and adjudicators for Rx Billing requests supporting REMS registration verification activities via a billing request transaction. .



Registration Verification via 5.1 Rx Billing Request
Diagram # 1

The entities depicted in the diagram above are arranged and defined below based on function. Depending on the REMS implementation a single entity may perform one or more of the functions. Examples may include but are not limited to the following:

- The Switch may also be the processor of Rx Billing, Service Billing, & Reversal requests support.
- The Switch may also perform the REMS Administration process.
- The REMS Administrator may be the Switch.
- The REMS Administrator may also adjudicate the service billing requests,
- The Product Reimbursement Adjudicator may also be the switch (e.g. cash claims).

A "(Dispensing) PROVIDER" may be a retail pharmacy, mail order pharmacy, specialty pharmacy, doctor's office, clinic, hospital, long-term care facility, or any other entity, which dispenses prescription drugs with a Risk Evaluation and Mitigation Strategy (REMS) registration verification requirement and ETASU. However, the subset of the above named dispensing providers that this Reference Guide addresses are those dispensers open to the public ("open door pharmacies") and some "closed door pharmacies" that typically submit a prescription billing or reversal request to a payer for processing and who's pharmacy practice management system supports the NCPDP *Telecommunication Standard Implementation Guide* (Version 5.1). This Reference Guide is not intended to be used for dispensing providers who bill using other standards or who dispense or administer REMS drugs in an inpatient or office setting or as part of a procedure.

The "SWITCH" receives Rx Billing, Service Billing, and Reversal request transactions from providers and intermediaries as they pass these requests from providers to adjudicators. Switching companies accept Rx Billing, Service Billing, and Reversal requests, optionally perform format conversions, and optionally perform pre-edits. The switch passes the request transactions to the appropriate processor or returns an approved response if the transaction is for a "cash" prescription. The reply from the processor also passes through the switch on its return to the provider.

The "REMS ADMINISTRATOR" executes the pharmaceutical manufacturer's REMS program. Upon receipt of the prescription billing request, the REMS Administrator determines if the dispensing provider, prescriber, and/or patient registration verification activities have been completed, if patient consultation is required, etc. The REMS Administrator may support program reporting, record keeping, auditing, or authorizations of services, such as performing drug utilization review reporting or program adherence reporting for the REMS. It is important to note that the REMS Administrator must ensure a consistent process model, whereby the purpose of REMS is achieved. A standard process should be developed to ensure safe-use specifically for a multi-source (innovator and generic) or "Class wide" REMS and direct all transactions to a single REMS Administrator, regardless of the number of manufacturers.

An "INTERMEDIARY" may be used by dispensing providers to transmit their Rx Billing and Service Billing claims to a claims processor. Intermediaries receive Rx Billing, Service Billing, and Reversal requests from switches or dispensing providers, perform editing/messaging and then either pass the request transactions to the appropriate switch or processor or return a denied transaction response to the providers. The reply from the processor also may pass to an intermediary for editing, messaging, or data capture on its return to the dispensing provider.

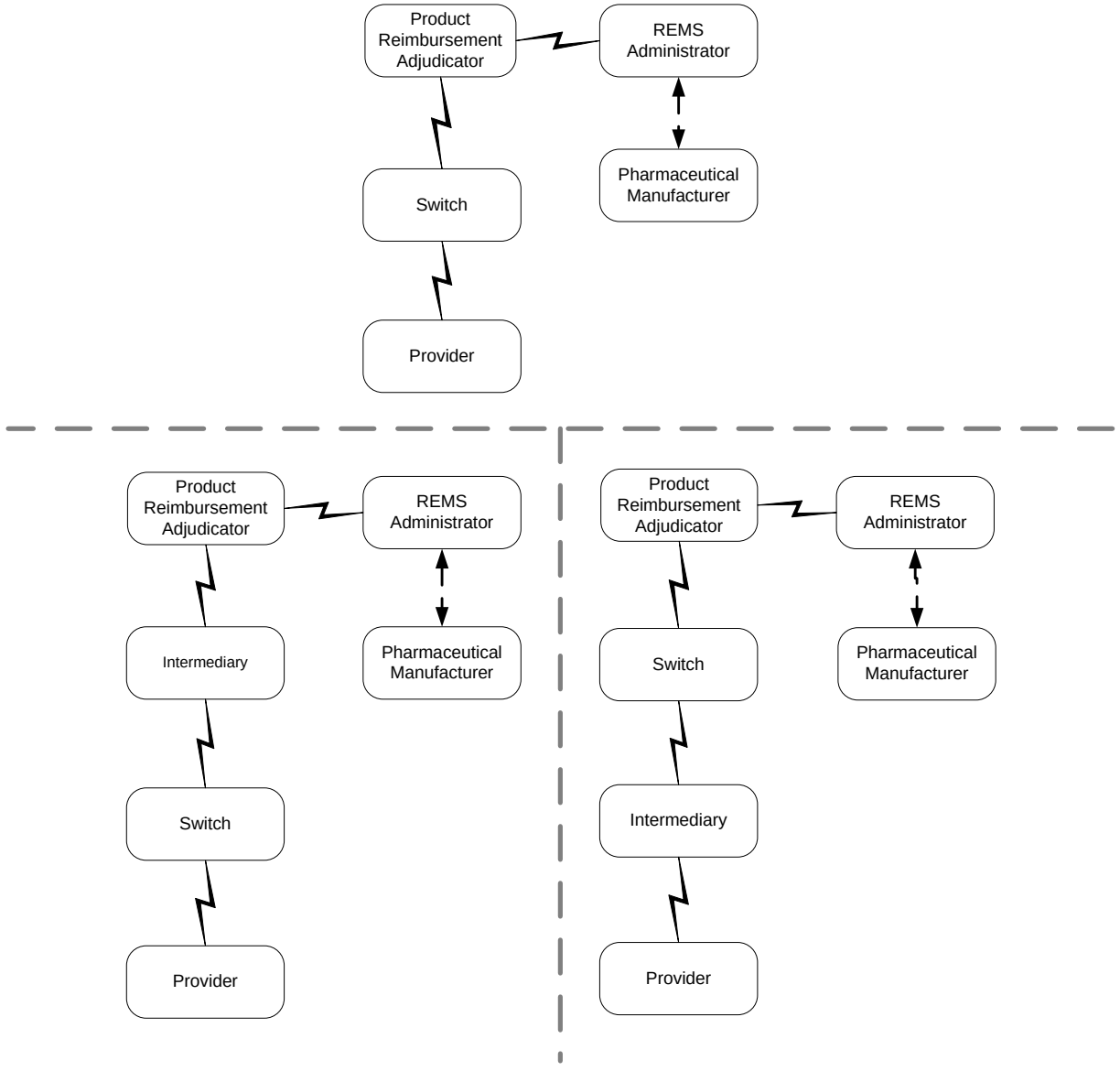
The "PRODUCT REIMBURSEMENT ADJUDICATOR" receives drug, medical supply or professional service transactions, applies rules regarding reimbursement based on contracted benefits, and responds to the submitted request.

The "PHARMACEUTICAL MANUFACTURER" develops, produces, and markets drugs or devices licensed for use as medications. The pharmaceutical manufacturer is responsible for the REMS and for contracting with the REMS Administrator.

Counseling Documentation via 5.1 Billing Transaction

The diagram below illustrates the typical business environments in which the NCPDP *Telecommunication Standard Implementation Guide* (Version 5.1) is employed between providers and Service Reimbursement Adjudicators for Service Billing requests supporting REMS counseling documentation activities via a billing request transaction.

Counseling Documentation is via the 5.1 "Billing" transaction (i.e. Transaction Code = "B1") and not a "Service Billing" transaction (i.e. Transaction Code = "S1") that is defined in a future version of the Telecommunication Standard.



Counseling Documentation via 5.1 Rx Billing Request
Diagram # 2

The entities depicted in the diagram above are arranged and defined below based on function. Depending on the REMS implementation a single entity may perform one or more of the functions. Examples may include but are not limited to the following:

- The service reimbursement adjudicator may also be the switch
- The service reimbursement adjudicator may also be the REMS Administrator

A "PROVIDER" may be a retail pharmacy, mail order pharmacy, specialty pharmacy, doctor's office, clinic, hospital, long-term care facility, or any other entity, which dispenses prescription drugs with a Risk Evaluation and Mitigation Strategy (REMS) registration verification requirement and submits a prescription billing request (i.e. Service Billing) to the pharmaceutical manufacturer via the REMS Administration process.

The "SWITCH" receives Rx Billing, Service Billing, and Reversal request transactions from providers and intermediaries as they pass these requests from providers to adjudicators. Switching companies accept Rx Billing, Service Billing, and Reversal requests, optionally perform format conversions, and optionally perform pre-edits. The switch passes the request transactions to the appropriate processor or returns an approved response if the transaction is for a "cash" prescription. The reply from the processor also may pass through the switch on its return to the provider.

An "INTERMEDIARY" may be used by providers to transmit their Rx Billing and Service Billing claims to a "SERVICE REIMBURSEMENT ADJUDICATOR". Intermediaries receive Rx Billing, Service Billing, and Reversal requests from switches or providers, perform editing/messaging and then either pass the request transactions to the appropriate switch or processor or return a denied transaction response to the providers. The reply from the processor also may pass to an intermediary for editing, messaging, or data capture on its return to the provider.

The "SERVICE REIMBURSEMENT ADJUDICATOR" receives drug, medical supply or professional service transactions, applies rules regarding reimbursement based on contracted benefits, and responds to the submitted request.

The "PHARMACEUTICAL MANUFACTURER" develops, produces, and markets drugs or devices licensed for use as medications. The pharmaceutical manufacturer is responsible for the REMS.

3.3 REMS ADMINISTRATION PROCESS RESPONSIBILITIES

When using this standard, the Provider, Switch, Intermediary, and the REMS Processor are expected to perform specific functions, as outlined below:

3.3.1 PROVIDER

At a high-level, the Provider (dispenser) is responsible for the following when using a prescription billing or reversal request transaction and simultaneously requesting registration verification:

- Populating all mandatory fields for the request transmissions
- Populating all fields required by the adjudicator (payer sheet)
- Submitting all optional segments required by the REMS Administrator (REMS program sheet)
- Populating all optional fields required by the REMS Administrator (REMS program sheet)
- Using the same routing paths for associated transactions (billing and reversal).

3.3.2 REMS ADMINISTRATION PROCESS

At a high-level, the REMS Administration process includes some or all of the following:

- Interpreting requests and responding as needed to provide the maximum amount of information for error correction and resolution when required.
- Performing pharmacy registration verification edits before the billing request is delivered to the adjudicator or (dispensing) provider
- Performing prescriber registration verification edits before the billing request is delivered to the adjudicator or provider
- Performing patient registration verification edits before the billing request is delivered to the adjudicator or provider
- Performing pharmacist registration verification edits before the billing request is delivered to the adjudicator or provider
- Performing clinical appropriateness edits before the billing request is delivered to the adjudicator or provider
- Optionally capturing billing and billing reversal activity subsequent to the adjudicator processing the request
- Optionally processing service billing requests
- Optionally matching service billing requests to their associated registration verification requests
- Optionally performing data capture and reporting activities on behalf of the REMS sponsor.

3.3.3 RESPONSIBILITIES OF THE SWITCH

At a high-level, the Switch is responsible for the following:

- Routing qualified billing transactions for proprietary REMS registration verification
- Interpreting REMS Administration response as a Data Capture Only, Denial or Approval status.
- Optionally, delivering the submitted billing request to the adjudicator when the Registration Verification Response is a Data Capture Only or Approval status.
- Optionally, formatting and delivering a Registration Verification Denial to the provider
- Routing qualified reversal transactions for proprietary REMS registration verification

4. BUSINESS FUNCTIONS

4.1 INTRODUCTION

This section describes the different business functional transactions defined in this standard. It is not expected that all transaction types or functions will be used by all providers, switches, intermediaries, or REMS Administrators. Each individual REMS program will determine transaction type and business function usage.

The transaction functions include:

1. Registration Verification via Rx Billing Transaction
2. Clinical Appropriateness via Rx Billing Transaction
3. Dispensing Activity Reporting via Rx Billing and Reversal Transactions
4. Patient Counseling Billing via Service Billing Transaction

4.2 REGISTRATION VERIFICATION VIA RX BILLING TRANSACTION

A provider may submit a billing request to the intended payer of the claim. Upon receipt of the billing request the REMS Administrator may perform any combination of the following registration verification edits:

- Patient Registration Verification – The REMS Administrator may compare submitted patient information to patient registry data for the intended medication. A REMS patient registry is used for REMS with ETASU to ensure the patient is certified to receive the intended medication. The billing request passes to the intended payer if the patient matches an entry on the patient registry and all other REMS business function edits are successful. If called for in the REMS, the billing request may be denied with a REMS specific message if the patient information does not match an entry on the REMS patient registry.

- Prescriber Registration Verification – The REMS Administrator may compare submitted prescriber information to prescriber registry data for the intended medication. A REMS prescriber registry is used for REMS with ETASU to ensure the prescriber is certified to prescribe the intended medication. The billing request passes to the intended payer if the prescriber matches an entry on the prescriber registry and all other REMS business function edits are successful. If called for in the specific REMS, the billing request is may be denied with a REMS specific message if the prescriber information does not match an entry on the REMS prescriber registry.

- Pharmacy or Dispenser Registration Verification – The REMS Administrator may compare submitted pharmacy and/or pharmacist information to pharmacy/pharmacist registry data for the intended medication. A REMS pharmacy/pharmacist registry is used for REMS with ETASU to ensure the pharmacy and/or pharmacist is certified to dispense the intended medication. The billing request passes to the intended payer if the pharmacy/pharmacist matches an entry on the pharmacy/pharmacist registry and all other REMS business function edits are successful. If called for in the specific REMS, the billing request may be denied with a REMS specific message if the pharmacy/pharmacist information does not match an entry on the REMS pharmacy/pharmacist registry.

4.3 CLINICAL APPROPRIATENESS VIA RX BILLING TRANSACTION/SWITCH AS REMS ADMINISTRATOR

When the switch is the REMS Administrator, a dispensing provider may submit a billing request to the intended payer of the claim. Upon receipt of the billing request the switch may perform clinical appropriateness edits as the REMS Administrator:

- Clinical Appropriateness Edits – The REMS Administration process may compare submitted patient and claim data to validate dispensing appropriateness. The validation of the submitted claim and patient data is used to ensure medication appropriateness. The billing request passes to the intended payer if the submitted patient and claim data pass the clinical appropriate edits for the specific REMS program. The billing request may be denied with a REMS specific message if the submitted patient and claim data fail the clinical appropriateness edits for the REMS program.

4.4 DISPENSING ACTIVITY REPORTING VIA RX BILLING AND REVERSAL TRANSACTIONS

A provider may submit a billing request to the intended payer or reversal request to the payer of a previously paid claim. Processor responses to billing and reversal requests may be used to report prescription dispensing activity. Dispensing activity may be captured as follows:

- Prescription Billing Requests – The REMS Administration process may be required to capture/report prescription dispensing activity. The dispensing activity may be captured/reported via billing and reversal transactions. When the claim processor approves the billing request (i.e. Transaction Status Response is "P" (Paid) or "C" (Captured)) the REMS Administration process will capture the Quantity Dispensed and assume the prescription is dispensed. When the claim processor denies the billing request (i.e. Transaction Response Status is "R" (Rejected)) the REMS Administration process does not capture the Quantity Dispensed and assumes the prescription is not dispensed.

- Prescription Reversal Requests – Again, the REMS Administration process may be required to capture/report prescription dispensing activity. The dispensing activity may be captured/reported via billing and reversal transactions. When the claim processor approves the reversal request (i.e. Transaction Status Response is "A" (Approved) the REMS Administration process captures the Quantity Dispensed and assumes the prescription is not dispensed.

4.5 REGISTRATION VERIFICATION VIA RX BILLING TRANSACTION

When a dispensing provider submits a billing request to the intended payer of the claim, the REMS Administration process may support any of the following:

- Patient Registration Verification – The REMS Administration process may compare submitted patient information to patient registry data for the intended medication. A REMS patient registry is used to ensure the patient is certified to receive the intended medication. The REMS Administration process will approve or deny the patient registration verification. The switch passes the billing request to the processor if the REMS Administration response resulted in an approval. The switch delivers a denied response to the provider if the REMS Administration process resulted in a denial.

- Prescriber Registration Verification – The REMS Administration process may compare submitted physician information to prescriber registry data for the intended medication. A REMS prescriber registry is used to ensure the prescriber is certified to prescribe the intended medication. The REMS Administration process will approve or deny the prescriber registration verification. The switch passes the billing request to the processor if the REMS Administration

response resulted in an approval. The switch delivers a denied response to the provider if the REMS Administration process resulted in a denial.

- Pharmacy or Dispenser Registration Verification – The REMS Administration process may compare submitted pharmacy and/or pharmacist information to pharmacy/pharmacist registry data for the intended medication. The REMS pharmacy/pharmacist registry is used to ensure the pharmacy and/or pharmacist is certified to dispense the intended medication. The REMS Administration process will approve or deny the pharmacy or dispenser registration verification. The switch passes the billing request to the processor if the REMS Administration response was an approval. The switch delivers a denied response to the provider if the REMS Administration process resulted in a denial. .

4.6 CLINICAL APPROPRIATENESS VIA RX BILLING TRANSACTION

When a provider submits a billing request to the intended payer of the claim, the REMS Administration process may support any of the following:

- Clinical Appropriateness Edits – The REMS Administration process may compare submitted patient and claim data to validate dispensing appropriateness. The validation of the submitted claim and patient data is used to ensure medication appropriateness. The REMS Administration process will approve or deny the clinical appropriateness. The switch passes the billing request to the processor if the REMS Administrator response was an approval. The switch delivers a denied response to the provider if the REMS Administration process resulted in a denial

4.7 DISPENSING ACTIVITY REPORTING VIA RX BILLING TRANSACTION AND REVERSAL TRANSACTIONS

A provider may submit a billing request to the intended payer or reversal request to the payer of previously paid claim. Processor responses to billing and reversal requests may be used to report prescription dispensing activity. Dispensing activity may be captured as follows:

- Prescription Billing Requests – The REMS Administration process may be required to capture/report prescription dispensing activity. The dispensing activity may be captured/reported via billing and reversal transactions. A Transaction Status Response = “P” (Paid) or “C” (Captured)) from the processor will be interpreted by the REMS Administration process as the prescription was dispensed.

- Prescription Reversal Requests – The REMS Administration process may be required to capture/report prescription dispensing activity. The dispensing activity may be captured/reported via billing and reversal transactions. A Transaction Status Response = “A” (Approved) from the processor will be interpreted by the REMS Administration process as the prescription was not dispensed.

4.8 PATIENT COUNSELING BILLING VIA SERVICE BILLING TRANSACTION

A provider may submit a billing request for a patient counseling associated with the dispensing of a REMS product.

5. TRANSACTION STRUCTURE

5.1 GENERAL INFORMATION

The REMS Administrator is expected to provide program participation sheets for supported REMS programs. The REMS program participation sheets will align with the referenced NCPDP Telecommunication Standard Implementation Guide, Data Dictionary, and External Code List.

5.2 VERSION 5.1 – REGISTRATION VERIFICATION VIA BILLING – SEGMENT DISCUSSION

Registration Verification, via a billing request, requires the pharmacy software provider to compare the payer sheet to program participation requirements for a REMS programs. Optional Telecommunication Standard Version 5.1 segments that may be required to support REMS program participation requirements include the following:

Request Segments

Segment:	Usage:
Patient	The Patient Segment may be used by the REMS Administrator to validate patient registration
Pharmacy Provider	The Pharmacy Provider Segment may be used by the REMS Administrator to validate pharmacist participation/certification requirements
Prescriber	The Prescriber Segment may be used by the REMS Administrator to validate prescriber program participation/certification requirements
DUR/PPS	The DUR/PPS Segment may be used by the REMS Administrator to capture pharmacy documented counseling activities
Clinical	The Clinical Segment may be used by the REMS Administrator to validate prescription appropriateness

Response Segments

Segment:	Usage:
Response Status	The Response Status Segment may be used by the REMS Administrator to communicate approval (e.g. Authorization Number) or denial (e.g. Prescriber Not Registered) information.
Response DUR/PPS	The Response DUR/PPS Segment may be used by the REMS Administrator to communicate any clinical information to the pharmacy

5.3 VERSION 5.1 – REGISTRATION VERIFICATION VIA BILLING – DATA ELEMENT DISCUSSION

Registration Verification, via a billing request, requires the pharmacy software provider to compare the payer sheet to program participation requirements of any REMS programs. Optional Telecommunication Standard Version 5.1 fields that may be used to support REMS participation requirements include the following:

Billing Request

Request Fields:	Segment:	Usage:
Patient ID Qualifier	Patient	May be used during the REMS Administration process to identify the patient or report activity.
Patient ID	Patient	May be used during the REMS Administration process to identify the patient or report activity
Date of Birth	Patient	May be used during the REMS Administration process to identify the patient or report activity

Request Fields:	Segment:	Usage:
Patient Gender Code	Patient	May be used during the REMS Administration process to identify the patient or report activity
Patient First Name	Patient	May be used during the REMS Administration process to identify the patient or report activity
Patient Last Name	Patient	May be used during the REMS Administration process to identify the patient or report activity
Patient Street Address	Patient	May be used during the REMS Administration process to identify the patient or report activity
Patient City Address	Patient	May be used during the REMS Administration process to identify the patient or report activity
Patient State/Province Address	Patient	May be used during the REMS Administration process to identify the patient or report activity
Patient ZIP/Postal Zone	Patient	May be used during the REMS Administration process to identify the patient or report activity
Product Service ID Qualifier	Claim	May be used during the REMS Administration process to qualify the billing request for registration verification activity
Product Service ID	Claim	Used to qualify the billing request for registration verification activity
Quantity Dispensed	Claim	May be used during the REMS Administration process to perform clinical appropriateness or report activity
Days Supply	Claim	May be used during the REMS Administration process to perform clinical appropriateness or report activity
Fill Number	Claim	May be used during the REMS Administration process to perform clinical appropriateness or report activity
Prescriber ID	Prescriber	May be used during the REMS Administration process to identify the prescriber or report activity
Prescriber Last Name	Prescriber	May be used during the REMS Administration process to identify the prescriber or report activity
Service Provider ID Qualifier	Pharmacy Provider	May be used during the REMS Administration process to identify the type of identifier for the responsible pharmacist
Service Provider ID	Pharmacy Provider	May be used during the REMS Administration process to identify the pharmacist
Professional Service Fee Submitted	Pricing	May be used during the REMS Administration process to identify the expected reimbursement amount for the service
Gross Amount Due	Pricing	May be used during the REMS Administration process to identify the expected reimbursement amount for all activities

Billing Request Response – Reject Denial

Response Fields:	Segment:	Usage:
Reject Count	Response Status	May be used during the REMS Administration process to indicate the number of reject codes that follow
Reject Code	Response Status	May be used during the REMS Administration process to communicate one or more reject codes
Additional Message Information	Response Status	May be use during the REMS Administration process to communicate additional information that clarifies the reason for the denial

Billing Request Response – Paid/Approval

Response Fields:	Segment:	Usage:
Additional Message Information	Response Status	May be used during the REMS Administration process to communicate a REMS program participation authorization number

5.4 VERSION 5.1 – REMS SERVICE BILLING – SEGMENT DISCUSSION

A Service Billing, for a REMS counseling session, requires the pharmacy software provider to support a "Service Billing" for participating REMS programs that require documentation and billing of REMS counseling activities. Optional Telecommunication Standard Version 5.1 segments that may be required to support the documentation and billing of a REMS counseling session include the following:

Segment:	Usage:
Transaction Header	The Transaction Header will be used to identify the routing information for the service billing.
Patient	The Patient Segment will be used by the provider to identify the patient receiving the service.
Insurance	The Insurance Segment will not be used during the REMS Administration process.
Claim	The Claim Segment is required for a service billing. The segment will be used by the Provider to identify the associated prescription billing request.
DUR/PPS	The DUR/PPS will be used by the provider to document the professional services performed and outcome of those services.
Pricing	The Pricing Segment will be used by the provider to request payment for services.

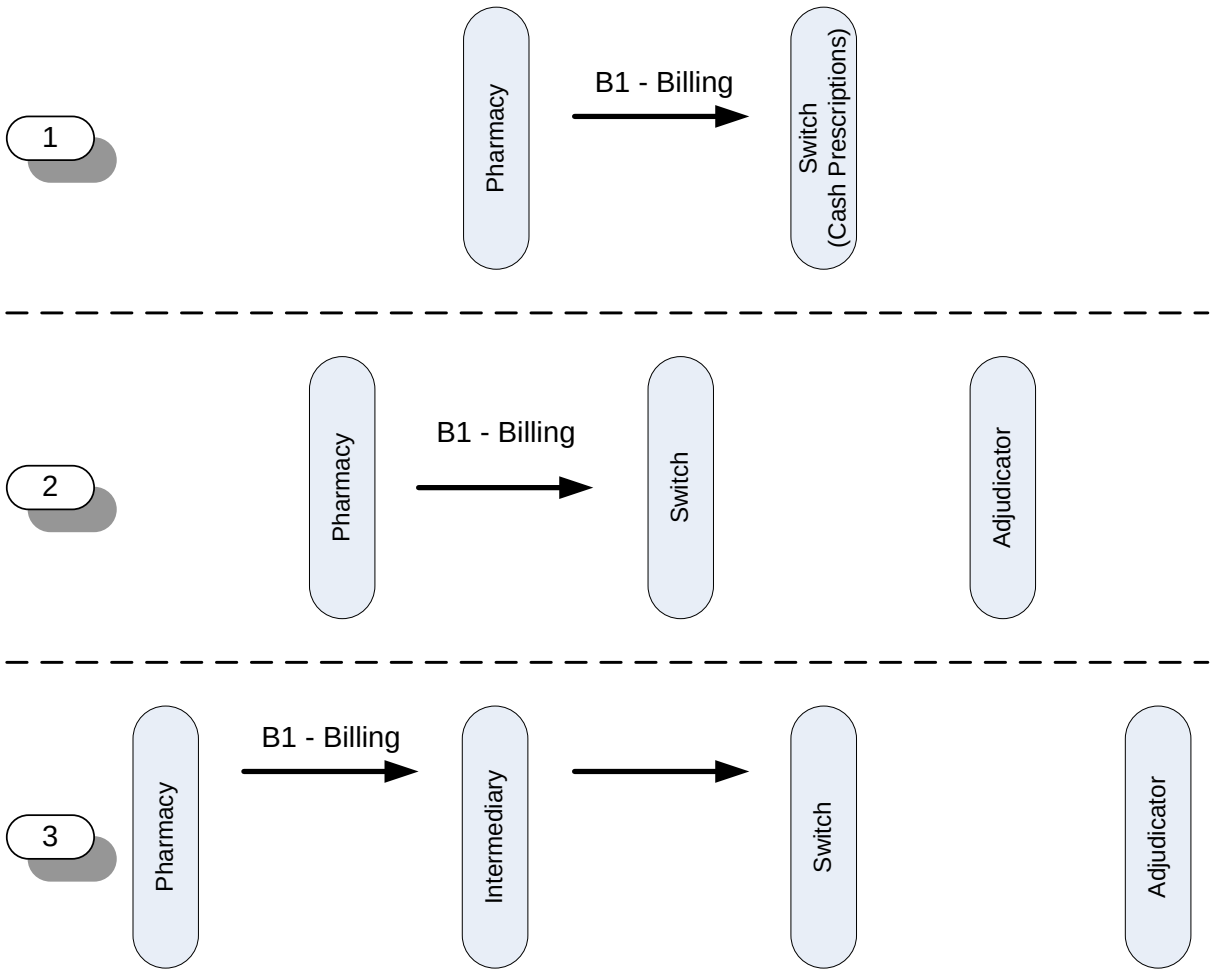
5.5 VERSION 5.1 – REMS SERVICE BILLING – DATA ELEMENT DISCUSSION

A Service Billing, for a REMS counseling session, requires the pharmacy software provider to format a transaction according to the payer sheet defined by the REMS program administrator. Telecommunication Standard Version 5.1 fields that may be used to support the documentation and billing of a REMS counseling activity include the following:

Request Fields:	Segment:	Usage:
BIN Number	Transaction Header	Used to identify the routing information for the REMS Administrator
Patient ID	Patient	May be used during the REMS Administration process to identify the patient
Date of Birth	Patient	May be used during the REMS Administration process to identify the patient
Patient Gender Code	Patient	May be used during the REMS Administration process to identify the patient
Patient First Name	Patient	May be used during the REMS Administration process to identify the patient
Patient Last Name	Patient	May be used during the REMS Administration process to identify the patient
Patient Street Address	Patient	May be used during the REMS Administration process to identify the patient
Patient City Address	Patient	May be used during the REMS Administration process to identify the patient
Patient State/Province Address	Patient	May be used during the REMS Administration process to identify the patient
Patient ZIP/Postal Zone	Patient	May be used during the REMS Administration process to identify the patient
Product/Service ID Qualifier	Claim	Will be used during the REMS Administration process to identify the transaction is a Service Billing
Associated Prescription/Service Reference Number	Claim	Will be used during the REMS Administration process to identify the corresponding prescription
Associated Prescription/Service Date	Claim	Will be used during the REMS Administration process to identify the corresponding date of service
Reason for Service Code	DUR/PPS	May be used during the REMS Administration process to identify the reason for the professional service
Professional Service Code	DUR/PPS	May be used during the REMS Administration process to identify the professional service
Result of Service Code	DUR/PPS	May be used during the REMS Administration process to identify the outcome of the service
DUR/PPS Level of Effort	DUR/PPS	May be used during the REMS Administration process to identify the level of effort to perform the service
Professional Service Fee Submitted	Pricing	Will be used to identify the requested professional service fee
Gross Amount Due	Pricing	Will be used to identify an expected reimbursement amount

6. TRANSACTION EXAMPLES

6.1 5.1 RX BILLING REQUEST



Standard billing fields are black font. The fields applicable to REMS are shown in the "REMS Situation" column with example data as a guide to the implementer. Situational or Optional Segments and fields are shown as a guide to the implementer, but would not be sent in a compliant transaction unless data was present.
REMS fields of interest are *italicized shaded.*

	TRANSACTION HEADER SEGMENT		MANDATORY SEGMENT
Field	**Field Name**	**Mandatory or Optional**	**REMS Situation**
1Ø1-A1	BIN NUMBER	M	*61ØØ66*
1Ø2-A2	VERSION/RELEASE NUMBER	M	*5.1*
1Ø3-A3	TRANSACTION CODE	M	*B1*
1Ø4-A4	PROCESSOR CONTROL NUMBER	M	*1234567890*
1Ø9-A9	TRANSACTION COUNT	M	*1*
2Ø2-B2	SERVICE PROVIDER ID QUALIFIER	M	*Ø7*

	TRANSACTION HEADER SEGMENT		MANDATORY SEGMENT
Field	**Field Name**	**Mandatory or Optional**	**REMS Situation**
2Ø1-B1	SERVICE PROVIDER ID	M	*1234567*
4Ø1-D1	DATE OF SERVICE	M	*2Ø1ØØ815*
11Ø-AK	SOFTWARE VENDOR/CERTIFICATION ID	M	*98765bbbbb*

	PATIENT SEGMENT		SITUATIONAL SEGMENT
Field	**Field Name**	**Mandatory or Optional**	**REMS Situation**
111-AM	SEGMENT IDENTIFICATION	M	*Ø1*
331-CX	*PATIENT ID QUALIFIER*	*O*	*99*
332-CY	*PATIENT ID*	*O*	*123456789*
3Ø4-C4	*DATE OF BIRTH*	*O*	*1962Ø615*
3Ø5-C5	*PATIENT GENDER CODE*	*O*	*1*
31Ø-CA	*PATIENT FIRST NAME*	*O*	*John*
311-CB	*PATIENT LAST NAME*	*O*	*Doe*
322-CM	*PATIENT STREET ADDRESS*	*O*	*1313 Mockingbird Lane*
323-CN	*PATIENT CITY ADDRESS*	*O*	*Phoenix*
324-CO	*PATIENT STATE/PROVINCE ADDRESS*	*O*	*AZ*
325-CP	*PATIENT ZIP/POSTAL ZONE*	*O*	*8526Ø*
326-CQ	*PATIENT PHONE NUMBER*	*O*	*6234658923*
3Ø7-C7	PATIENT LOCATION	O	*Ø*
333-CZ	EMPLOYER ID	O	*5ØZ123*
334-1C	SMOKER/NON-SMOKER CODE	O	*1*
335-2C	PREGNANCY INDICATOR	O	*b*

	INSURANCE SEGMENT		MANDATORY SEGMENT
Field	**Field Name**	**Mandatory or Optional**	**REMS Situation**
111-AM	SEGMENT IDENTIFICATION	M	*Ø4*
3Ø2-C2	CARDHOLDER ID	M	*123456789*
312-CC	CARDHOLDER FIRST NAME	O	*John*
313-CD	CARDHOLDER LAST NAME	O	*Doe*
314-CE	HOME PLAN	O	*bbb*
524-FO	PLAN ID	O	*bbbbbbbb*
3Ø9-C9	ELIGIBILITY CLARIFICATION CODE	O	*Ø*
336-8C	FACILITY ID	O	*bbbbbbbbbb*
3Ø1-C1	GROUP ID	O	*CMPD1234567*
3Ø3-C3	PERSON CODE	O	*ØØ1*
3Ø6-C6	PATIENT RELATIONSHIP CODE	O	*1*

	CLAIM SEGMENT		MANDATORY SEGMENT
Field	**Field Name**	**Mandatory or Optional**	**REMS Situation**
111-AM	SEGMENT IDENTIFICATION	M	*Ø7*
455-EM	PRESCRIPTION/SERVICE REFERENCE NUMBER QUALIFIER	M	*1*
4Ø2-D2	PRESCRIPTION/SERVICE REFERENCE NUMBER	M	*1234567*
436-E1	*PRODUCT/SERVICE ID QUALIFIER*	*M*	*Ø3*
4Ø7-D7	*PRODUCT/SERVICE ID*	*M*	*ØØØØ2554Ø13*
456-EN	ASSOCIATED PRESCRIPTION/SERVICE REFERENCE NUMBER	O	
457-EP	ASSOCIATED PRESCRIPTION/SERVICE DATE	O	
458-SE	PROCEDURE MODIFIER CODE COUNT	O	
459-ER	PROCEDURE MODIFIER CODE	O***R***	

	CLAIM SEGMENT		MANDATORY SEGMENT
Field	**Field Name**	**Mandatory or Optional**	**REMS Situation**
442-E7	*QUANTITY DISPENSED*	*O*	*3Ø*
4Ø3-D3	*FILL NUMBER*	*O*	*ØØ*
4Ø5-D5	*DAYS SUPPLY*	*O*	*3Ø*
4Ø6-D6	COMPOUND CODE	O	*1*
4Ø8-D8	DISPENSE AS WRITTEN (DAW)/PRODUCT SELECTION CODE	O	*Ø*
414-DE	DATE PRESCRIPTION WRITTEN	O	*2Ø1ØØ815*
415-DF	NUMBER OF REFILLS AUTHORIZED	O	*Ø1*
419-DJ	PRESCRIPTION ORIGIN CODE	O	*1*
354-NX	SUBMISSION CLARIFICATION CODE COUNT	O	
42Ø-DK	SUBMISSION CLARIFICATION CODE	O	
46∅-ET	QUANTITY PRESCRIBED	O	*3Ø*
3Ø8-C8	OTHER COVERAGE CODE	O	*Ø*
453-EJ	ORIGINALLY PRESCRIBED PRODUCT/SERVICE ID QUALIFIER	O	
445-EA	ORIGINALLY PRESCRIBED PRODUCT/SERVICE CODE	O	
446-EB	ORIGINALLY PRESCRIBED QUANTITY	O	
33Ø-CW	ALTERNATE ID	O	
454-EK	SCHEDULED PRESCRIPTION ID NUMBER	O	
6ØØ-28	UNIT OF MEASURE	O	*EA*
418-DI	LEVEL OF SERVICE	O	
461-EU	PRIOR AUTHORIZATION TYPE CODE	O	
462-EV	PRIOR AUTHORIZATION NUMBER SUBMITTED	O	
463-EW	INTERMEDIARY AUTHORIZATION TYPE ID	O	
464-EX	INTERMEDIARY AUTHORIZATION ID	O	
343-HD	DISPENSING STATUS	O	
344-HF	QUANTITY INTENDED TO BE DISPENSED	O	
345-HG	DAYS SUPPLY INTENDED TO BE DISPENSED	O	

	PHARMACY PROVIDER SEGMENT		SITUATIONAL SEGMENT
Field	**Field Name**	**Mandatory or Optional**	**REMS Situation**
111-AM	SEGMENT IDENTIFICATION	M	
465-EY	*PROVIDER ID QUALIFIER*	*O*	*Ø5*
444-E9	*PROVIDER ID*	*O*	*4864864*

	PRESCRIBER SEGMENT		SITUATIONAL SEGMENT
Field	**Field Name**	**Mandatory or Optional**	**REMS Situation**
111-AM	SEGMENT IDENTIFICATION	M	
466-EZ	*PRESCRIBER ID QUALIFIER*	*O*	*Ø1*
411-DB	*PRESCRIBER ID*	*O*	*8796Ø413*
467-IE	PRESCRIBER LOCATION CODE	O	
427-DR	*PRESCRIBER LAST NAME*	*O*	*Smith*
498-PM	PRESCRIBER PHONE NUMBER	O	
468-2E	PRIMARY CARE PROVIDER ID QUALIFIER	O	
421-DL	PRIMARY CARE PROVIDER ID	O	
469-H5	PRIMARY CARE PROVIDER LOCATION CODE	O	
47Ø-4E	PRIMARY CARE PROVIDER LAST NAME	O	

	COORDINATION OF BENEFITS/OTHER PAYMENTS SEGMENT		SITUATIONAL SEGMENT

Field	Field Name	Mandatory or Optional	REMS Situation
111-AM	SEGMENT IDENTIFICATION	M	
337-4C	COORDINATION OF BENEFITS/OTHER PAYMENTS COUNT	M	
338-5C	OTHER PAYER COVERAGE TYPE	M***R***	
339-6C	OTHER PAYER ID QUALIFIER	O***R***	
34Ø-7C	OTHER PAYER ID	O***R***	
443-E8	OTHER PAYER DATE	O***R***	
341-HB	OTHER PAYER AMOUNT PAID COUNT	O	
342-HC	OTHER PAYER AMOUNT PAID QUALIFIER	O***R***	
431-DV	OTHER PAYER AMOUNT PAID	O***R***	
471-5E	OTHER PAYER REJECT COUNT	O	
472-6E	OTHER PAYER REJECT CODE	O***R***	

	WORKERS' COMPENSATION SEGMENT		**SITUATIONAL SEGMENT**
Field	**Field Name**	**Mandatory or Optional**	**REMS Situation**
111-AM	SEGMENT IDENTIFICATION	M	
434-DY	DATE OF INJURY	M	
315-CF	EMPLOYER NAME	O	
316-CG	EMPLOYER STREET ADDRESS	O	
317-CH	EMPLOYER CITY ADDRESS	O	
318-CI	EMPLOYER STATE/PROVINCE ADDRESS	O	
319-CJ	EMPLOYER ZIP/POSTAL ZONE	O	
32Ø-CK	EMPLOYER PHONE NUMBER	O	
321-CL	EMPLOYER CONTACT NAME	O	
327-CR	CARRIER ID	O	
435-DZ	CLAIM/REFERENCE ID	O	

	DUR/PPS SEGMENT		**SITUATIONAL SEGMENT**
Field	**Field Name**	**Mandatory or Optional**	**REMS Situation**
111-AM	SEGMENT IDENTIFICATION	M	
473-7E	DUR/PPS CODE COUNTER	O***R***	
439-E4	REASON FOR SERVICE CODE	O***R***	
44Ø-E5	PROFESSIONAL SERVICE CODE	O***R***	
441-E6	RESULT OF SERVICE CODE	O***R***	
474-8E	DUR/PPS LEVEL OF EFFORT	O***R***	
475-J9	DUR CO-AGENT ID QUALIFIER	O***R***	
476-H6	DUR CO-AGENT ID	O***R***	

	PRICING SEGMENT		**MANDATORY SEGMENT**
Field	**Field Name**	**Mandatory or Optional**	**REMS Situation**
111-AM	SEGMENT IDENTIFICATION	M	
4Ø9-D9	INGREDIENT COST SUBMITTED	O	
412-DC	DISPENSING FEE SUBMITTED	O	
477-BE	PROFESSIONAL SERVICE FEE SUBMITTED	O	
433-DX	PATIENT PAID AMOUNT SUBMITTED	O	
438-E3	INCENTIVE AMOUNT SUBMITTED	O	
478-H7	OTHER AMOUNT CLAIMED SUBMITTED COUNT	O	
479-H8	OTHER AMOUNT CLAIMED SUBMITTED QUALIFIER	O***R***	
48Ø-H9	OTHER AMOUNT CLAIMED SUBMITTED	O***R***	
481-HA	FLAT SALES TAX AMOUNT SUBMITTED	O	

	PRICING SEGMENT		MANDATORY SEGMENT
Field	**Field Name**	**Mandatory or Optional**	**REMS Situation**
482-GE	PERCENTAGE SALES TAX AMOUNT SUBMITTED	O	
483-HE	PERCENTAGE SALES TAX RATE SUBMITTED	O	
484-JE	PERCENTAGE SALES TAX BASIS SUBMITTED	O	
426-DQ	USUAL AND CUSTOMARY CHARGE	O	
43Ø-DU	GROSS AMOUNT DUE	O	
423-DN	BASIS OF COST DETERMINATION	O	

	COUPON SEGMENT		SITUATIONAL SEGMENT
Field	**Field Name**	**Mandatory or Optional**	**REMS Situation**
111-AM	SEGMENT IDENTIFICATION	M	
485-KE	COUPON TYPE	M	
486-ME	COUPON NUMBER	M	
487-NE	COUPON VALUE AMOUNT	O	

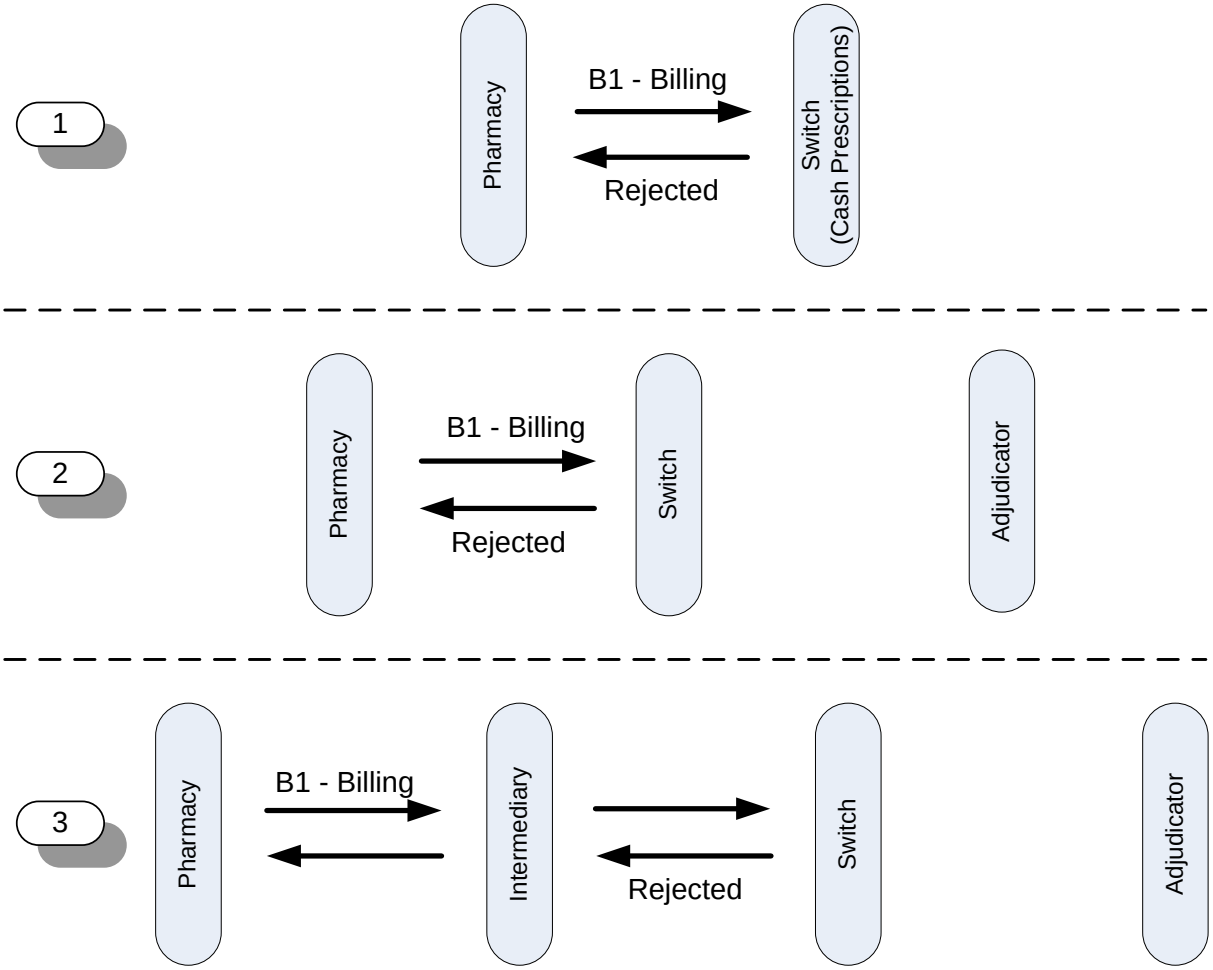
	COMPOUND SEGMENT		SITUATIONAL SEGMENT
Field	**Field Name**	**Mandatory or Optional**	**REMS Situation**
111-AM	SEGMENT IDENTIFICATION	M	
45Ø-EF	COMPOUND DOSAGE FORM DESCRIPTION CODE	M	
451-EG	COMPOUND DISPENSING UNIT FORM INDICATOR	M	
452-EH	COMPOUND ROUTE OF ADMINISTRATION	M	
447-EC	COMPOUND INGREDIENT COMPONENT COUNT	M	
488-RE	COMPOUND PRODUCT ID QUALIFIER	M***R***	
489-TE	COMPOUND PRODUCT ID	M***R***	
448-ED	COMPOUND INGREDIENT QUANTITY	M***R***	
449-EE	COMPOUND INGREDIENT DRUG COST	O***R***	
49Ø-UE	COMPOUND INGREDIENT BASIS OF COST DETERMINATION	O***R***	

	PRIOR AUTHORIZATION SEGMENT		SITUATIONAL SEGMENT
Field	**Field Name**	**Mandatory or Optional**	**REMS Situation**
111-AM	SEGMENT IDENTIFICATION	M	
498-PA	REQUEST TYPE	M	
498-PB	REQUEST PERIOD DATE-BEGIN	M	
498-PC	REQUEST PERIOD DATE-END	M	
498-PD	BASIS OF REQUEST	M	
498-PE	AUTHORIZED REPRESENTATIVE FIRST NAME	O	
498-PF	AUTHORIZED REPRESENTATIVE LAST NAME	O	
498-PG	AUTHORIZED REPRESENTATIVE STREET ADDRESS	O	
498-PH	AUTHORIZED REPRESENTATIVE CITY ADDRESS	O	
498-PJ	AUTHORIZED REPRESENTATIVE STATE/PROVINCE ADDRESS	O	
498-PK	AUTHORIZED REPRESENTATIVE ZIP/POSTAL ZONE	O	
498-PY	PRIOR AUTHORIZATION NUMBE—ASSIGNED	O	
5Ø3-F3	AUTHORIZATION NUMBER	O	
498-PP	PRIOR AUTHORIZATION SUPPORTING DOCUMENTATION	O	

	CLINICAL SEGMENT		SITUATIONAL SEGMENT

Field	Field Name	Mandatory or Optional	REMS Situation
111-AM	SEGMENT IDENTIFICATION	M	
491-VE	DIAGNOSIS CODE COUNT	O	
492-WE	DIAGNOSIS CODE QUALIFIER	O***R***	
424-DO	DIAGNOSIS CODE	O***R***	
493-XE	*CLINICAL INFORMATION COUNTER*	*O***R****	*Ø1*
494-ZE	*MEASUREMENT DATE*	*O***R****	*2Ø1ØØ8115*
495-H1	*MEASUREMENT TIME*	*O***R****	*14ØØ*
496-H2	*MEASUREMENT DIMENSION*	*O***R****	*14 (Weight)*
497-H3	*MEASUREMENT UNIT*	*O***R****	*Ø3 (Pounds)*
499-H4	*MEASUREMENT VALUE*	*O***R****	*15Ø*

6.1.1 REMS ADJUDICATION PROCESS RESULTS IN A DENIAL



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REMS fields of interest are *italicized shaded.*

	RESPONSE HEADER SEGMENT		MANDATORY SEGMENT
Field	**Field Name**	**Mandatory or Optional**	**REMS Situation**
1Ø2-A2	VERSION/RELEASE NUMBER	M	5.1
1Ø3-A3	TRANSACTION CODE	M	B1
1∅9-A9	TRANSACTION COUNT	M	1
5Ø1-F1	HEADER RESPONSE STATUS	M	A
2Ø2-B2	SERVICE PROVIDER ID QUALIFIER	M	Ø7
2Ø1-B1	SERVICE PROVIDER ID	M	1234567
4Ø1-D1	DATE OF SERVICE	M	2Ø1ØØ815

	RESPONSE MESSAGE SEGMENT		OPTIONAL SEGMENT
Field	**Field Name**	**Mandatory or Optional**	**REMS Situation**
111-AM	SEGMENT IDENTIFICATION	M	
5Ø4-F4	MESSAGE	O	

	RESPONSE INSURANCE SEGMENT		OPTIONAL SEGMENT
Field	**Field Name**	**Mandatory or Optional**	**REMS Situation**
111-AM	SEGMENT IDENTIFICATION	M	
3Ø1-C1	GROUP ID	O	
524-FO	PLAN ID	O	
545-2F	NETWORK REIMBURSEMENT ID	O	
568-J7	PAYER ID QUALIFIER	O	
569-J8	PAYER ID	O	

Transaction Level

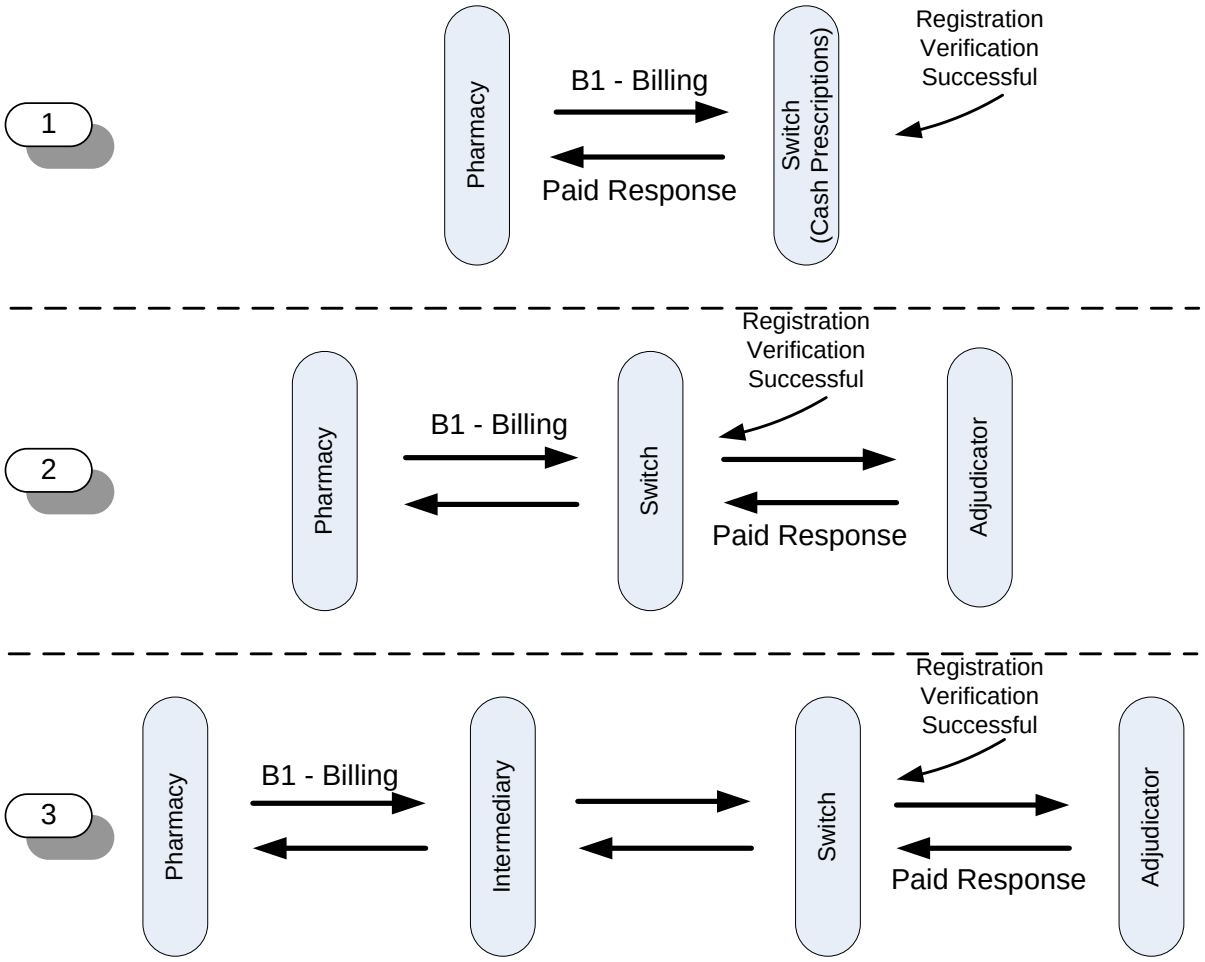
	RESPONSE STATUS SEGMENT		MANDATORY SEGMENT
Field	**Field Name**	**Mandatory or Optional**	**REMS Situation**
111-AM	SEGMENT IDENTIFICATION	M	
112-AN	TRANSACTION RESPONSE STATUS	M	R
5Ø3-F3	AUTHORIZATION NUMBER	O	
51Ø-FA	*REJECT COUNT*	*O*	*1*
511-FB	*REJECT CODE*	*O***R****	*NN (Transaction Rejected at Switch or Intermediary)*
546-4F	REJECT FIELD OCCURRENCE INDICATOR	O***R***	
547-5F	APPROVED MESSAGE CODE COUNT	O	
548-6F	APPROVED MESSAGE CODE	O***R***	
526-FQ	*ADDITIONAL MESSAGE INFORMATION*	*O*	*REMS Administrator – Non-Matched Patient*
549-7F	*HELP DESK PHONE NUMBER QUALIFIER*	*O*	*Ø1*
55∅-8F	*HELP DESK PHONE NUMBER*	*O*	*8ØØ4561234*

	RESPONSE CLAIM SEGMENT		MANDATORY SEGMENT
Field	**Field Name**	**Mandatory or Optional**	**REMS Situation**
111-AM	SEGMENT IDENTIFICATION	M	
455-EM	PRESCRIPTION/SERVICE REFERENCE NUMBER QUALIFIER	M	
4Ø2-D2	PRESCRIPTION/SERVICE REFERENCE NUMBER	M	
551-9F	PREFERRED PRODUCT COUNT	O	
552-AP	PREFERRED PRODUCT ID QUALIFIER	O***R***	
553-AR	PREFERRED PRODUCT ID	O***R***	
554-AS	PREFERRED PRODUCT INCENTIVE	O***R***	

	RESPONSE CLAIM SEGMENT		MANDATORY SEGMENT
Field	**Field Name**	**Mandatory or Optional**	**REMS Situation**
555-AT	PREFERRED PRODUCT COPAY INCENTIVE	O***R***	
556-AU	PREFERRED PRODUCT DESCRIPTION	O***R***	

	RESPONSE DUR/PPS SEGMENT		OPTIONAL SEGMENT
Field	**Field Name**	**Mandatory or Optional**	**REMS Situation**
111-AM	SEGMENT IDENTIFICATION	M	
567-J6	DUR/PPS RESPONSE CODE COUNTER	O***R***	
439-E4	REASON FOR SERVICE CODE	O***R***	
528-FS	CLINICAL SIGNIFICANCE CODE	O***R***	
529-FT	OTHER PHARMACY INDICATOR	O***R***	
53Ø-FU	PREVIOUS DATE OF FILL	O***R***	
531-FV	QUANTITY OF PREVIOUS FILL	O***R***	
532-FW	DATABASE INDICATOR	O***R***	
533-FX	OTHER PRESCRIBER INDICATOR	O***R***	

6.1.2 REMS ADMINISTRATION PROCESS RESULTS IN AN APPROVAL/ PROCESSOR RETURNS A PAID RESPONSE



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REMS fields of interest are *italicized shaded.*

	RESPONSE HEADER SEGMENT		**MANDATORY SEGMENT**
Field	**Field Name**	**Mandatory or Optional**	**REMS Situation**
1Ø2-A2	VERSION/RELEASE NUMBER	M	5.1
1Ø3-A3	TRANSACTION CODE	M	B1
1∅9-A9	TRANSACTION COUNT	M	1
5Ø1-F1	HEADER RESPONSE STATUS	M	A
2Ø2-B2	SERVICE PROVIDER ID QUALIFIER	M	Ø7
2Ø1-B1	SERVICE PROVIDER ID	M	1234567
4Ø1-D1	DATE OF SERVICE	M	2Ø1ØØ815

	RESPONSE MESSAGE SEGMENT		OPTIONAL SEGMENT
Field	**Field Name**	**Mandatory or Optional**	**REMS Situation**
111-AM	SEGMENT IDENTIFICATION	M	
5Ø4-F4	MESSAGE	O	

	RESPONSE INSURANCE SEGMENT		OPTIONAL SEGMENT
Field	**Field Name**	**Mandatory or Optional**	**REMS Situation**
111-AM	SEGMENT IDENTIFICATION	M	
3Ø1-C1	GROUP ID	O	
524-FO	PLAN ID	O	
545-2F	NETWORK REIMBURSEMENT ID	O	
568-J7	PAYER ID QUALIFIER	O	
569-J8	PAYER ID	O	

Transaction Level

	RESPONSE STATUS SEGMENT		MANDATORY SEGMENT
Field	**Field Name**	**Mandatory or Optional**	**REMS Situation**
111-AM	SEGMENT IDENTIFICATION	M	
112-AN	TRANSACTION RESPONSE STATUS	M	P,D
5Ø3-F3	AUTHORIZATION NUMBER	O	
51Ø-FA	REJECT COUNT	O	
511-FB	REJECT CODE	O***R***	
546-4F	REJECT FIELD OCCURRENCE INDICATOR	O***R***	
547-5F	APPROVED MESSAGE CODE COUNT	O	
548-6F	APPROVED MESSAGE CODE	O***R***	
526-FQ	*ADDITIONAL MESSAGE INFORMATION*	*O*	*REMS AUTH # A123456*
549-7F	HELP DESK PHONE NUMBER QUALIFIER	O	
55∅-8F	HELP DESK PHONE NUMBER	O	

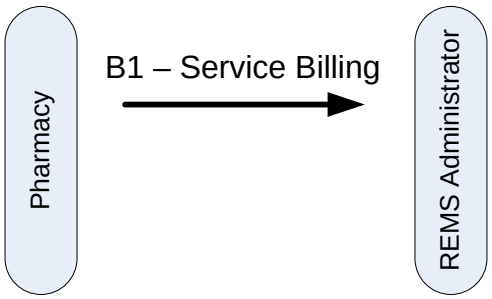
	RESPONSE CLAIM SEGMENT		MANDATORY SEGMENT
Field	**Field Name**	**Mandatory or Optional**	**REMS Situation**
111-AM	SEGMENT IDENTIFICATION	M	
455-EM	PRESCRIPTION/SERVICE REFERENCE NUMBER QUALIFIER	M	
4Ø2-D2	PRESCRIPTION/SERVICE REFERENCE NUMBER	M	
551-9F	PREFERRED PRODUCT COUNT	O	
552-AP	PREFERRED PRODUCT ID QUALIFIER	O***R***	
553-AR	PREFERRED PRODUCT ID	O***R***	
554-AS	PREFERRED PRODUCT INCENTIVE	O***R***	
555-AT	PREFERRED PRODUCT COPAY INCENTIVE	O***R***	
556-AU	PREFERRED PRODUCT DESCRIPTION	O***R***	

	RESPONSE PRICING SEGMENT		MANDATORY SEGMENT
Field	**Field Name**	**Mandatory or Optional**	**REMS Situation**
111-AM	SEGMENT IDENTIFICATION	M	
5Ø5-F5	PATIENT PAY AMOUNT	O	
5Ø6-F6	INGREDIENT COST PAID	O	
5Ø7-F7	DISPENSING FEE PAID	O	

	RESPONSE PRICING SEGMENT		MANDATORY SEGMENT
Field	**Field Name**	**Mandatory or Optional**	**REMS Situation**
557-AV	TAX EXEMPT INDICATOR	O	
558-AW	FLAT SALES TAX AMOUNT PAID	O	
559-AX	PERCENTAGE SALES TAX AMOUNT PAID	O	
56∅-AY	PERCENTAGE SALES TAX RATE PAID	O	
561-AZ	PERCENTAGE SALES TAX BASIS PAID	O	
521-FL	INCENTIVE AMOUNT PAID	O	
562-J1	PROFESSIONAL SERVICE FEE PAID	O	
563-J2	OTHER AMOUNT PAID COUNT	O	
564-J3	OTHER AMOUNT PAID QUALIFIER	O***R***	
565-J4	OTHER AMOUNT PAID	O***R***	
566-J5	OTHER PAYER AMOUNT RECOGNIZED	O	
5Ø9-F9	TOTAL AMOUNT PAID	O	
522-FM	BASIS OF REIMBURSEMENT DETERMINATION	O	
523-FN	AMOUNT ATTRIBUTED TO SALES TAX	O	
512-FC	ACCUMULATED DEDUCTIBLE AMOUNT	O	
513-FD	REMAINING DEDUCTIBLE AMOUNT	O	
514-FE	REMAINING BENEFIT AMOUNT	O	
517-FH	AMOUNT APPLIED TO PERIODIC DEDUCTIBLE	O	
518-FI	AMOUNT OF COPAY/CO-INSURANCE	O	
519-FJ	AMOUNT ATTRIBUTED TO PRODUCT SELECTION	O	
52Ø-FK	AMOUNT EXCEEDING PERIODIC BENEFIT MAXIMUM	O	
346-HH	BASIS OF CALCULATION—DISPENSING FEE	O	
347-HJ	BASIS OF CALCULATION—COPAY	O	
348-HK	BASIS OF CALCULATION—FLAT SALES TAX	O	
349-HM	BASIS OF CALCULATION—PERCENTAGE SALES TAX	O	

	RESPONSE DUR/PPS SEGMENT		OPTIONAL SEGMENT
Field	**Field Name**	**Mandatory or Optional**	**REMS Situation**
111-AM	SEGMENT IDENTIFICATION	M	
567-J6	DUR/PPS RESPONSE CODE COUNTER	O***R***	
439-E4	REASON FOR SERVICE CODE	O***R***	
528-FS	CLINICAL SIGNIFICANCE CODE	O***R***	
529-FT	OTHER PHARMACY INDICATOR	O***R***	
53Ø-FU	PREVIOUS DATE OF FILL	O***R***	
531-FV	QUANTITY OF PREVIOUS FILL	O***R***	
532-FW	DATABASE INDICATOR	O***R***	
533-FX	OTHER PRESCRIBER INDICATOR	O***R***	

6.2 5.1 REMS ADMINISTRATION COUNSELING DOCUMENTATION BILLING



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REMS fields of interest are *italicized shaded.*

	TRANSACTION HEADER SEGMENT		MANDATORY SEGMENT
Field	**Field Name**	**Mandatory or Optional**	**REMS Situation**
1Ø1-A1	BIN NUMBER	M	*61ØØ66*
1Ø2-A2	VERSION/RELEASE NUMBER	M	*5.1*
1Ø3-A3	TRANSACTION CODE	M	*B1*
1Ø4-A4	PROCESSOR CONTROL NUMBER	M	*1234567890*
1Ø9-A9	TRANSACTION COUNT	M	*1*
2Ø2-B2	SERVICE PROVIDER ID QUALIFIER	M	*Ø7*
2Ø1-B1	SERVICE PROVIDER ID	M	*1234567*
4Ø1-D1	DATE OF SERVICE	M	*2Ø1ØØ815*
11Ø-AK	SOFTWARE VENDOR/CERTIFICATION ID	M	*98765bbbbb*

	PATIENT SEGMENT		SITUATIONAL SEGMENT
Field	**Field Name**	**Mandatory or Optional**	**REMS Situation**
111-AM	SEGMENT IDENTIFICATION	M	*Ø1*
331-CX	*PATIENT ID QUALIFIER*	*O*	*99*
332-CY	*PATIENT ID*	*O*	*123456789*
3Ø4-C4	*DATE OF BIRTH*	*O*	*1962Ø615*
3Ø5-C5	*PATIENT GENDER CODE*	*O*	*1*
31Ø-CA	*PATIENT FIRST NAME*	*O*	*John*
311-CB	*PATIENT LAST NAME*	*O*	*Doe*
322-CM	*PATIENT STREET ADDRESS*	*O*	*1313 Mockingbird Lane*
323-CN	*PATIENT CITY ADDRESS*	*O*	*Phoenix*
324-CO	*PATIENT STATE/PROVINCE ADDRESS*	*O*	*AZ*
325-CP	*PATIENT ZIP/POSTAL ZONE*	*O*	*8526Ø*
326-CQ	*PATIENT PHONE NUMBER*	*O*	*6234658923*
3Ø7-C7	PATIENT LOCATION	O	*Ø*
333-CZ	EMPLOYER ID	O	*5ØZ123*
334-1C	SMOKER/NON-SMOKER CODE	O	*1*
335-2C	PREGNANCY INDICATOR	O	*b*

	INSURANCE SEGMENT		MANDATORY SEGMENT
Field	**Field Name**	**Mandatory or Optional**	**REMS Situation**
111-AM	SEGMENT IDENTIFICATION	M	*Ø4*
3Ø2-C2	*CARDHOLDER ID*	*M*	*123456789*
312-CC	CARDHOLDER FIRST NAME	O	*John*
313-CD	CARDHOLDER LAST NAME	O	*Doe*
314-CE	HOME PLAN	O	*bbb*
524-FO	PLAN ID	O	*bbbbbbbb*
3Ø9-C9	ELIGIBILITY CLARIFICATION CODE	O	*Ø*
336-8C	FACILITY ID	O	*bbbbbbbbbb*
3Ø1-C1	GROUP ID	O	*CMPD1234567*
3Ø3-C3	PERSON CODE	O	*ØØ1*
3Ø6-C6	PATIENT RELATIONSHIP CODE	O	*1*

	CLAIM SEGMENT		MANDATORY SEGMENT
Field	**Field Name**	**Mandatory or Optional**	**REMS Situation**
111-AM	SEGMENT IDENTIFICATION	M	*Ø7*
455-EM	*PRESCRIPTION/SERVICE REFERENCE NUMBER QUALIFIER*	*M*	*2*
4Ø2-D2	*PRESCRIPTION/SERVICE REFERENCE NUMBER*	*M*	*1234568*
436-E1	*PRODUCT/SERVICE ID QUALIFIER*	*M*	*Ø6*
4Ø7-D7	*PRODUCT/SERVICE ID*	*M*	*Ø*
456-EN	*ASSOCIATED PRESCRIPTION/SERVICE REFERENCE NUMBER*	*O*	*1234567*
457-EP	*ASSOCIATED PRESCRIPTION/SERVICE DATE*	*O*	*2Ø1ØØ815*
458-SE	PROCEDURE MODIFIER CODE COUNT	O	
459-ER	PROCEDURE MODIFIER CODE	O***R***	
442-E7	QUANTITY DISPENSED	O	
4Ø3-D3	FILL NUMBER	O	
4Ø5-D5	DAYS SUPPLY	O	
4Ø6-D6	COMPOUND CODE	O	
4Ø8-D8	DISPENSE AS WRITTEN (DAW)/PRODUCT SELECTION CODE	O	
414-DE	DATE PRESCRIPTION WRITTEN	O	
415-DF	NUMBER OF REFILLS AUTHORIZED	O	
419-DJ	PRESCRIPTION ORIGIN CODE	O	
354-NX	SUBMISSION CLARIFICATION CODE COUNT	O	
42Ø-DK	SUBMISSION CLARIFICATION CODE	O	
46∅-ET	QUANTITY PRESCRIBED	O	
3Ø8-C8	OTHER COVERAGE CODE	O	
453-EJ	ORIGINALLY PRESCRIBED PRODUCT/SERVICE ID QUALIFIER	O	
445-EA	ORIGINALLY PRESCRIBED PRODUCT/SERVICE CODE	O	
446-EB	ORIGINALLY PRESCRIBED QUANTITY	O	
33Ø-CW	ALTERNATE ID	O	
454-EK	SCHEDULED PRESCRIPTION ID NUMBER	O	
6ØØ-28	UNIT OF MEASURE	O	
418-DI	LEVEL OF SERVICE	O	
461-EU	PRIOR AUTHORIZATION TYPE CODE	O	
462-EV	PRIOR AUTHORIZATION NUMBER SUBMITTED	O	
463-EW	INTERMEDIARY AUTHORIZATION TYPE ID	O	
464-EX	INTERMEDIARY AUTHORIZATION ID	O	
343-HD	DISPENSING STATUS	O	
344-HF	QUANTITY INTENDED TO BE DISPENSED	O	
345-HG	DAYS SUPPLY INTENDED TO BE DISPENSED	O	

	PHARMACY PROVIDER SEGMENT		SITUATIONAL SEGMENT
Field	**Field Name**	**Mandatory or Optional**	**REMS Situation**
111-AM	SEGMENT IDENTIFICATION	M	
465-EY	*PROVIDER ID QUALIFIER*	*O*	*Ø5*
444-E9	*PROVIDER ID*	*O*	*4864864*

	PRESCRIBER SEGMENT		SITUATIONAL SEGMENT
Field	**Field Name**	**Mandatory or Optional**	**REMS Situation**
111-AM	SEGMENT IDENTIFICATION	M	
466-EZ	PRESCRIBER ID QUALIFIER	O	
411-DB	PRESCRIBER ID	O	
467-IE	PRESCRIBER LOCATION CODE	O	
427-DR	PRESCRIBER LAST NAME	O	
498-PM	PRESCRIBER PHONE NUMBER	O	
468-2E	PRIMARY CARE PROVIDER ID QUALIFIER	O	
421-DL	PRIMARY CARE PROVIDER ID	O	
469-H5	PRIMARY CARE PROVIDER LOCATION CODE	O	
47Ø-4E	PRIMARY CARE PROVIDER LAST NAME	O	

	COORDINATION OF BENEFITS/OTHER PAYMENTS SEGMENT		SITUATIONAL SEGMENT
Field	**Field Name**	**Mandatory or Optional**	**REMS Situation**
111-AM	SEGMENT IDENTIFICATION	M	
337-4C	COORDINATION OF BENEFITS/OTHER PAYMENTS COUNT	M	
338-5C	OTHER PAYER COVERAGE TYPE	M***R***	
339-6C	OTHER PAYER ID QUALIFIER	O***R***	
34Ø-7C	OTHER PAYER ID	O***R***	
443-E8	OTHER PAYER DATE	O***R***	
341-HB	OTHER PAYER AMOUNT PAID COUNT	O	
342-HC	OTHER PAYER AMOUNT PAID QUALIFIER	O***R***	
431-DV	OTHER PAYER AMOUNT PAID	O***R***	
471-5E	OTHER PAYER REJECT COUNT	O	
472-6E	OTHER PAYER REJECT CODE	O***R***	

	WORKERS' COMPENSATION SEGMENT		SITUATIONAL SEGMENT
Field	**Field Name**	**Mandatory or Optional**	**REMS Situation**
111-AM	SEGMENT IDENTIFICATION	M	
434-DY	DATE OF INJURY	M	
315-CF	EMPLOYER NAME	O	
316-CG	EMPLOYER STREET ADDRESS	O	
317-CH	EMPLOYER CITY ADDRESS	O	
318-CI	EMPLOYER STATE/PROVINCE ADDRESS	O	
319-CJ	EMPLOYER ZIP/POSTAL ZONE	O	
32Ø-CK	EMPLOYER PHONE NUMBER	O	
321-CL	EMPLOYER CONTACT NAME	O	
327-CR	CARRIER ID	O	
435-DZ	CLAIM/REFERENCE ID	O	

	DUR/PPS SEGMENT		**SITUATIONAL SEGMENT**
Field	**Field Name**	**Mandatory or Optional**	**REMS Situation**
111-AM	SEGMENT IDENTIFICATION	M	
473-7E	*DUR/PPS CODE COUNTER*	*O***R****	*Ø1*
439-E4	*REASON FOR SERVICE CODE*	*O***R****	*ED (Patient Education/Instruction)*
44Ø-E5	*PROFESSIONAL SERVICE CODE*	*O***R****	*PE (Patient Education/Instruction)*
441-E6	*RESULT OF SERVICE CODE*	*O***R****	*3K (Instructions Understood)*
474-8E	DUR/PPS LEVEL OF EFFORT	O***R***	
475-J9	DUR CO-AGENT ID QUALIFIER	O***R***	
476-H6	DUR CO-AGENT ID	O***R***	

	PRICING SEGMENT		**MANDATORY SEGMENT**
Field	**Field Name**	**Mandatory or Optional**	**REMS Situation**
111-AM	SEGMENT IDENTIFICATION	M	
4Ø9-D9	INGREDIENT COST SUBMITTED	O	
412-DC	DISPENSING FEE SUBMITTED	O	
477-BE	*PROFESSIONAL SERVICE FEE SUBMITTED*	*O*	*$5.ØØ*
433-DX	PATIENT PAID AMOUNT SUBMITTED	O	
438-E3	INCENTIVE AMOUNT SUBMITTED	O	
478-H7	OTHER AMOUNT CLAIMED SUBMITTED COUNT	O	
479-H8	OTHER AMOUNT CLAIMED SUBMITTED QUALIFIER	O***R***	
48Ø-H9	OTHER AMOUNT CLAIMED SUBMITTED	O***R***	
481-HA	FLAT SALES TAX AMOUNT SUBMITTED	O	
482-GE	PERCENTAGE SALES TAX AMOUNT SUBMITTED	O	
483-HE	PERCENTAGE SALES TAX RATE SUBMITTED	O	
484-JE	PERCENTAGE SALES TAX BASIS SUBMITTED	O	
426-DQ	USUAL AND CUSTOMARY CHARGE	O	
43Ø-DU	*GROSS AMOUNT DUE*	*O*	*$5.ØØ*
423-DN	BASIS OF COST DETERMINATION	O	

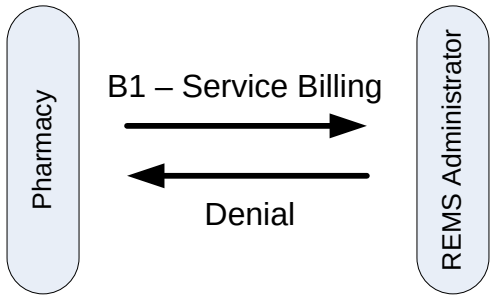
	COUPON SEGMENT		**SITUATIONAL SEGMENT**
Field	**Field Name**	**Mandatory or Optional**	**REMS Situation**
111-AM	SEGMENT IDENTIFICATION	M	
485-KE	COUPON TYPE	M	
486-ME	COUPON NUMBER	M	
487-NE	COUPON VALUE AMOUNT	O	

	COMPOUND SEGMENT		**SITUATIONAL SEGMENT**
Field	**Field Name**	**Mandatory or Optional**	**REMS Situation**
111-AM	SEGMENT IDENTIFICATION	M	
45Ø-EF	COMPOUND DOSAGE FORM DESCRIPTION CODE	M	
451-EG	COMPOUND DISPENSING UNIT FORM INDICATOR	M	
452-EH	COMPOUND ROUTE OF ADMINISTRATION	M	
447-EC	COMPOUND INGREDIENT COMPONENT COUNT	M	
488-RE	COMPOUND PRODUCT ID QUALIFIER	M***R***	
489-TE	COMPOUND PRODUCT ID	M***R***	
448-ED	COMPOUND INGREDIENT QUANTITY	M***R***	
449-EE	COMPOUND INGREDIENT DRUG COST	O***R***	
49Ø-UE	COMPOUND INGREDIENT BASIS OF COST DETERMINATION	O***R***	

	PRIOR AUTHORIZATION SEGMENT		SITUATIONAL SEGMENT
Field	**Field Name**	**Mandatory or Optional**	**REMS Situation**
111-AM	SEGMENT IDENTIFICATION	M	
498-PA	REQUEST TYPE	M	
498-PB	REQUEST PERIOD DATE-BEGIN	M	
498-PC	REQUEST PERIOD DATE-END	M	
498-PD	BASIS OF REQUEST	M	
498-PE	AUTHORIZED REPRESENTATIVE FIRST NAME	O	
498-PF	AUTHORIZED REPRESENTATIVE LAST NAME	O	
498-PG	AUTHORIZED REPRESENTATIVE STREET ADDRESS	O	
498-PH	AUTHORIZED REPRESENTATIVE CITY ADDRESS	O	
498-PJ	AUTHORIZED REPRESENTATIVE STATE/PROVINCE ADDRESS	O	
498-PK	AUTHORIZED REPRESENTATIVE ZIP/POSTAL ZONE	O	
498-PY	PRIOR AUTHORIZATION NUMBE—ASSIGNED	O	
5Ø3-F3	AUTHORIZATION NUMBER	O	
498-PP	PRIOR AUTHORIZATION SUPPORTING DOCUMENTATION	O	

	CLINICAL SEGMENT		SITUATIONAL SEGMENT
Field	**Field Name**	**Mandatory or Optional**	**REMS Situation**
111-AM	SEGMENT IDENTIFICATION	M	
491-VE	DIAGNOSIS CODE COUNT	O	
492-WE	DIAGNOSIS CODE QUALIFIER	O***R***	
424-DO	DIAGNOSIS CODE	O***R***	
493-XE	CLINICAL INFORMATION COUNTER	O***R***	
494-ZE	MEASUREMENT DATE	O***R***	
495-H1	MEASUREMENT TIME	O***R***	
496-H2	MEASUREMENT DIMENSION	O***R***	
497-H3	MEASUREMENT UNIT	O***R***	
499-H4	MEASUREMENT VALUE	O***R***	

6.2.1 REMS ADMINISTRATION COUNSELING DOCUMENTATION BILLING -DENIED RESPONSE



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are shown as a guide to the implementer, but would not be sent in a compliant transaction unless data was present.
REMS fields of interest are *italicized shaded.*

	RESPONSE HEADER SEGMENT		**MANDATORY SEGMENT**
Field	**Field Name**	**Mandatory or Optional**	**REMS Situation**
1Ø2-A2	VERSION/RELEASE NUMBER	M	5.1
1Ø3-A3	TRANSACTION CODE	M	B1
1∅9-A9	TRANSACTION COUNT	M	1
5Ø1-F1	HEADER RESPONSE STATUS	M	A
2Ø2-B2	SERVICE PROVIDER ID QUALIFIER	M	Ø7
2Ø1-B1	SERVICE PROVIDER ID	M	1234567
4Ø1-D1	DATE OF SERVICE	M	2Ø1ØØ815

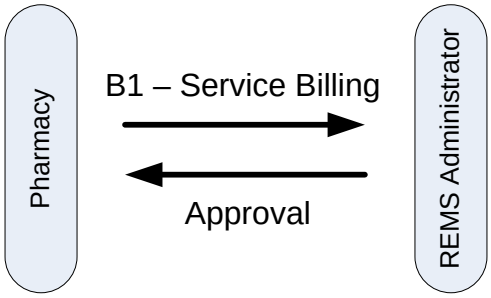
	RESPONSE MESSAGE SEGMENT		**OPTIONAL SEGMENT**
Field	**Field Name**	**Mandatory or Optional**	**REMS Situation**
111-AM	SEGMENT IDENTIFICATION	M	
5Ø4-F4	MESSAGE	O	

	RESPONSE INSURANCE SEGMENT		**OPTIONAL SEGMENT**
Field	**Field Name**	**Mandatory or Optional**	**REMS Situation**
111-AM	SEGMENT IDENTIFICATION	M	
3Ø1-C1	GROUP ID	O	
524-FO	PLAN ID	O	
545-2F	NETWORK REIMBURSEMENT ID	O	
568-J7	PAYER ID QUALIFIER	O	
569-J8	PAYER ID	O	

Transaction Level

	RESPONSE STATUS SEGMENT		**MANDATORY SEGMENT**
Field	**Field Name**	**Mandatory or Optional**	**REMS Situation**
111-AM	SEGMENT IDENTIFICATION	M	
112-AN	TRANSACTION RESPONSE STATUS	M	R (Rejected)
5Ø3-F3	AUTHORIZATION NUMBER	O	
51Ø-FA	*REJECT COUNT*	*O*	*1*
511-FB	*REJECT CODE*	*O***R****	*NN (Transaction Rejected at Switch or Intermediary)*
546-4F	REJECT FIELD OCCURRENCE INDICATOR	O***R***	
547-5F	APPROVED MESSAGE CODE COUNT	O	
548-6F	APPROVED MESSAGE CODE	O***R***	
526-FQ	*ADDITIONAL MESSAGE INFORMATION*	*O*	*REMS Administrator – Non-Matched Patient/Associated Rx*
549-7F	*HELP DESK PHONE NUMBER QUALIFIER*	*O*	*Ø1*
55∅-8F	*HELP DESK PHONE NUMBER*	*O*	*8ØØ4561234*

6.2.2 REMS ADMINISTRATION COUNSELING DOCUMENTATION BILLING RESPONSE – APPROVED RESPONSE



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REMS fields of interest are *italicized shaded.*

	RESPONSE HEADER SEGMENT		MANDATORY SEGMENT
Field	**Field Name**	**Mandatory or Optional**	**REMS Situation**
1Ø2-A2	VERSION/RELEASE NUMBER	M	5.1
1Ø3-A3	TRANSACTION CODE	M	B1
1∅9-A9	TRANSACTION COUNT	M	1
5Ø1-F1	HEADER RESPONSE STATUS	M	A
2Ø2-B2	SERVICE PROVIDER ID QUALIFIER	M	Ø7
2Ø1-B1	SERVICE PROVIDER ID	M	1234567
4Ø1-D1	DATE OF SERVICE	M	2Ø1ØØ815

	RESPONSE MESSAGE SEGMENT		OPTIONAL SEGMENT
Field	**Field Name**	**Mandatory or Optional**	**REMS Situation**
111-AM	SEGMENT IDENTIFICATION	M	
5Ø4-F4	MESSAGE	O	

	RESPONSE INSURANCE SEGMENT		OPTIONAL SEGMENT
Field	**Field Name**	**Mandatory or Optional**	**REMS Situation**
111-AM	SEGMENT IDENTIFICATION	M	
3Ø1-C1	GROUP ID	O	
524-FO	PLAN ID	O	
545-2F	NETWORK REIMBURSEMENT ID	O	
568-J7	PAYER ID QUALIFIER	O	
569-J8	PAYER ID	O	

Transaction Level

	RESPONSE STATUS SEGMENT		**MANDATORY SEGMENT**
Field	**Field Name**	**Mandatory or Optional**	**REMS Situation**
111-AM	SEGMENT IDENTIFICATION	M	
112-AN	TRANSACTION RESPONSE STATUS	M	P,D
5Ø3-F3	AUTHORIZATION NUMBER	O	
51Ø-FA	REJECT COUNT	O	
511-FB	REJECT CODE	O***R***	
546-4F	REJECT FIELD OCCURRENCE INDICATOR	O***R***	
547-5F	APPROVED MESSAGE CODE COUNT	O	
548-6F	APPROVED MESSAGE CODE	O***R***	
526-FQ	*ADDITIONAL MESSAGE INFORMATION*	*O*	*REMS AUTH # P123456*
549-7F	HELP DESK PHONE NUMBER QUALIFIER	O	
55∅-8F	HELP DESK PHONE NUMBER	O	

	RESPONSE CLAIM SEGMENT		**MANDATORY SEGMENT**
Field	**Field Name**	**Mandatory or Optional**	**REMS Situation**
111-AM	SEGMENT IDENTIFICATION	M	
455-EM	PRESCRIPTION/SERVICE REFERENCE NUMBER QUALIFIER	M	
4Ø2-D2	PRESCRIPTION/SERVICE REFERENCE NUMBER	M	
551-9F	PREFERRED PRODUCT COUNT	O	
552-AP	PREFERRED PRODUCT ID QUALIFIER	O***R***	
553-AR	PREFERRED PRODUCT ID	O***R***	
554-AS	PREFERRED PRODUCT INCENTIVE	O***R***	
555-AT	PREFERRED PRODUCT COPAY INCENTIVE	O***R***	
556-AU	PREFERRED PRODUCT DESCRIPTION	O***R***	

	RESPONSE PRICING SEGMENT		**MANDATORY SEGMENT**
Field	**Field Name**	**Mandatory or Optional**	**REMS Situation**
111-AM	SEGMENT IDENTIFICATION	M	
5Ø5-F5	PATIENT PAY AMOUNT	O	
5Ø6-F6	INGREDIENT COST PAID	O	
5Ø7-F7	DISPENSING FEE PAID	O	
557-AV	TAX EXEMPT INDICATOR	O	
558-AW	FLAT SALES TAX AMOUNT PAID	O	
559-AX	PERCENTAGE SALES TAX AMOUNT PAID	O	
56∅-AY	PERCENTAGE SALES TAX RATE PAID	O	
561-AZ	PERCENTAGE SALES TAX BASIS PAID	O	
521-FL	INCENTIVE AMOUNT PAID	O	
562-J1	*PROFESSIONAL SERVICE FEE PAID*	*O*	*5Ø{ ($5.ØØ)*
563-J2	OTHER AMOUNT PAID COUNT	O	
564-J3	OTHER AMOUNT PAID QUALIFIER	O***R***	
565-J4	OTHER AMOUNT PAID	O***R***	
566-J5	OTHER PAYER AMOUNT RECOGNIZED	O	
5Ø9-F9	*TOTAL AMOUNT PAID*	*O*	*5Ø{ ($5.ØØ)*
522-FM	BASIS OF REIMBURSEMENT DETERMINATION	O	
523-FN	AMOUNT ATTRIBUTED TO SALES TAX	O	
512-FC	ACCUMULATED DEDUCTIBLE AMOUNT	O	
513-FD	REMAINING DEDUCTIBLE AMOUNT	O	
514-FE	REMAINING BENEFIT AMOUNT	O	
517-FH	AMOUNT APPLIED TO PERIODIC DEDUCTIBLE	O	
518-FI	AMOUNT OF COPAY/CO-INSURANCE	O	

	RESPONSE PRICING SEGMENT		MANDATORY SEGMENT
Field	**Field Name**	**Mandatory or Optional**	**REMS Situation**
519-FJ	AMOUNT ATTRIBUTED TO PRODUCT SELECTION	O	
52Ø-FK	AMOUNT EXCEEDING PERIODIC BENEFIT MAXIMUM	O	
346-HH	BASIS OF CALCULATION—DISPENSING FEE	O	
347-HJ	BASIS OF CALCULATION—COPAY	O	
348-HK	BASIS OF CALCULATION—FLAT SALES TAX	O	
349-HM	BASIS OF CALCULATION—PERCENTAGE SALES TAX	O	

	RESPONSE DUR/PPS SEGMENT		OPTIONAL SEGMENT
Field	**Field Name**	**Mandatory or Optional**	**REMS Situation**
111-AM	SEGMENT IDENTIFICATION	M	
567-J6	DUR/PPS RESPONSE CODE COUNTER	O***R***	
439-E4	REASON FOR SERVICE CODE	O***R***	
528-FS	CLINICAL SIGNIFICANCE CODE	O***R***	
529-FT	OTHER PHARMACY INDICATOR	O***R***	
53Ø-FU	PREVIOUS DATE OF FILL	O***R***	
531-FV	QUANTITY OF PREVIOUS FILL	O***R***	
532-FW	DATABASE INDICATOR	O***R***	
533-FX	OTHER PRESCRIBER INDICATOR	O***R***	

7. FREQUENTLY ASKED QUESTIONS

7.1 How does a pharmacy support the described "registration verification" activities for a cash prescription?

This reference guide describes the scenario in which the REMS Administration process also supports registration verification for cash prescriptions. The proposed approach includes the submission of a prescription billing request where the REMS Administration process will perform the necessary registration verification or clinical appropriateness edits. A prescription billing request denial is communicated to the pharmacy if any of the registration verification or clinical appropriateness edits fail. A prescription billing request approval (e.g. "PAID") response is communicated to the pharmacy if the registration verification or clinical appropriateness passes.

7.2 What are the REMS participation options for specialty pharmacies, mail order pharmacies, or pharmacies that do not use a switch?

It's anticipated that the manufacturers will coordinate with the industry and support alternative registration verification and clinical appropriateness solutions for those pharmacies that do not support electronic billing.

7.3 For a REMS program, how does one identify the Pharmacist in Charge?

The Pharmacist in Charge (a.k.a. Responsible Site Pharmacist, when required by the REMS program) is the designated pharmacist responsible for all professional activities within the pharmacy.

7.4 Is there a recommended identifier type for the pharmacist?

The pharmaceutical sponsors, via a REMS program participation sheet will define the pharmacist identifier that is required to participate in the REMS program. It is anticipated that NPI will be used for this function.

7.5 Are there any special requirements for reversals?

A REMS program may require the reporting of dispensing activity. If this is a program participation requirement, the switch is the REMS Administrator, and the provider seeks to employ the automated capture of dispensing activity during the REMS Administration process via the switch, the provider must ensure that reversal requests are delivered to the same switch.

7.6 WHAT REJECT CODE LISTS WILL THE REMS ADMINISTRATION PROCESS USE TO SUPPORT REGISTRATION VERIFICATION AND CLINICAL APPROPRIATENESS EDITING DENIALS?

NCPDP Telecommunication Standard Version 5.1 supports an existing list of reject codes that must be utilized by the REMS Administrator. New codes, specific to REMS program initiatives, may be established in a subsequent version of the Telecommunication Standard. Providers must rely on the free-form text messages returned in the Additional Message Information (526-FQ) field.

7.7 WILL THE REMS ADMINISTRATION PROCESS SUPPORT REBILL TRANSACTIONS? IF "YES", HOW IS A REBILL TREATED FOR A PRODUCT WITH REMS REQUIREMENTS

It's anticipated that the REMS Administration process will support the processing of Rebill requests. For the purpose of registration verification, any registration verification requests associated to a B3 transaction will be processed the same way a B1 transaction is processed. For the purpose of clinical appropriateness edits, any clinical appropriateness requirements associated to a B3 transaction will be processed the same way a B1 transaction is processed. For the purpose of reporting dispensing activity, any dispensing activity associated to a B3 will be processed as if the transaction is a Billing (B1) and Reversal (B2) request.

7.8 IS THERE A STANDARD TRANSACTION FORMAT FOR REQUESTS AND RESPONSES ASSOCIATED TO THE REMS ADMINISTRATION PROCESS?

No, the request and response associated to the REMS Administration process and the Switch is via trading partner agreement for Telecommunication Standard Version 5.1. The transactions, both request and response, are real-time transmissions.

NCPDP recommends the following request and response formats:

Billing Request
- Transmission
  - Transaction Header Segment - Required
  - Patient Segment - Required
  - Insurance Segment – Not Communicated (Does not align with Billing Request)
- Transactions
  - Claim Segment - Required
  - Pharmacy Provider Segment - Optional
  - Prescriber Segment - Optional
  - COB/Other Payments Segment – Not Communicated
  - Workers' Compensation Segment – Not Communicated
  - DUR/PPS Segment - Optional
  - Pricing Segment – Not Communicated (Does not align with Billing Request)
  - Coupon Segment – Not Communicated
  - Compound Segment - Optional
  - Prior Authorization Segment – Not Communicated
  - Clinical Segment - Optional

Billing Response - Accepted – Paid or Captured:
- Transmission

Response Header Segment - Required
Response Message Segment - Optional
Response Insurance Segment – Not Communicated
Transaction
Response Status Segment - Required
Response Claim Segment - Required
Response Pricing Segment – Not Communicated (Does not align with Billing Request)
Response DUR/PPS Segment - Optional
Response Prior Authorization Segment – Not Communicated

Billing Response - Accepted – Rejected:
Transmission
Response Header Segment - Required
Response Message Segment - Optional
Response Insurance Segment – Not Communicated
Transaction
Response Status Segment - Required
Response Claim Segment - Required
Response Pricing Segment – Not Communicated
Response DUR/PPS Segment - Optional
Response Prior Authorization Segment – Not Communicated

Additional Guidance

- Transmissions should be limited to a single transaction. The Switch will need to enforce this guidance.
- The pharmaceutical manufacturers **must** provide guidance to the switch and to providers on how a time out condition should be handled by the switch.
- The REMS Administration process **must** use standard NCPDP Telecommunication Standard Reject Codes in combination with free-text information in the Additional Message Information field (526-FQ) on denials. Suggested Reject Codes (511-FB)/free text messages that may be used include:
  - "25 " M/I Prescriber ID/Prescriber Not Registered to REMS – Call (XXX) XXX-XXXX
  - "CY " M/I Patient ID/Patient ID to complete REMS Registration Verification
  - "NN " Transaction Rejected at Switch or Intermediary/REMS participation requirements not met. Call (XXX) XXX-XXXX
- The Switch **may** strip non-required fields from the request transaction to simplify the REMS Adjudication process.

7.9 IN THE FOREGOING PARTICIPANT MODELS (I.E. USING THE EXISTING NCPDP BILLING REQUEST) DOES THE NCPDP TELECOMMUNICATION STANDARD FORMAT SUPPORT OVERRIDES OF REMS ALERTS?

Yes, the NCPDP Telecommunication Standard supports the override of a REMS denial, when allowed by the program, via the Intermediary Authorization ID Type (463-EW) and Intermediary Authorization ID (464-EX) fields. For NCPDP Telecommunication Standard Version 5.1, NCPDP recommends using a value of "1" (Intermediary Authorization) in the Intermediary Authorization ID Type field for both of the identified participant models. For Intermediary Authorization ID, NCPDP recognizes that trading partners determine the appropriate value for this field.

An alternative approach is the use the Prior Authorization Type Code and Prior Authorization Number Submitted fields to override a program alert. For NCPDP Telecommunication Standard Version 5.1,

NCPDP recommends using a value of “0” (Not Specified) in the Prior Authorization Type Code field for both of the identified participant models.

Some REMS programs may require a hard stop in all instances and others may override any or specific alerts. The described override capabilities allow for a phased implementation of a REMS program. The override capability additionally provides the ability to audit compliance with REMS program requirements.

8. APPENDIX A. HISTORY OF REFERENCE GUIDE CHANGES

8.1 VERSION X.Y