



**Arkansas
BlueCross BlueShield**

An Independent Licensee of the Blue Cross and Blue Shield Association

**2011 Clinical Quality Assurance
And
Utilization Management Program
Arkansas Blue Cross Blue Shield**

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OVERVIEW

The Arkansas Blue Cross Blue Shield Clinical Quality Assurance (QA) and Utilization Management (UM) Program is designed to encourage safe and effective drug utilization, enhance beneficiaries' health outcomes and promote cost-effective drug benefit plan designs for the Medicare Part D plan sponsors that subcontract/delegate services to CVS Caremark Part D Services, LLC. This Program is built upon the requirements of the National Committee for Quality Assurance (NCQA), Utilization Review Accreditation Commission (d.b.a. American Accreditation Healthcare Commission) (URAC), Employee Retirement Income Security Act (ERISA), Centers for Medicare & Medicaid Services (CMS) and other applicable regulatory organizations.

Coordination of Clinical QA and UM processes involves communication among practitioners, pharmacists, beneficiaries, Medicare Part D plan sponsors and various other internal departments, including, but not limited to:

- Medical Affairs
- Clinical Services
- Clinical Program Development
- Clinical Services Operations
- Clinical Account Management
- Formulary Administration Services
- Operations Excellence
- Compliance and Integrity

CVS Caremark Part D Services, LLC is a wholly owned subsidiary of CaremarkRx, LLC, which is a subsidiary of CVS Caremark Corporation. CaremarkRx, LLC and its subsidiaries (collectively referred to as "Caremark") provide certain aspects of the QA and UM Program services described below.

PROGRAM GOALS

The goal of the Clinical QA and UM Program is to help ensure beneficiaries receive access to high quality prescription drug coverage and quality service and do so in compliance with CMS quality assurance requirements. The goal is accomplished through the following:

- Provide therapeutically appropriate drug intervention and formulary management recommendations to applicable Medicare Part D plan sponsors
- Support beneficiaries' access to the drugs prescribed by their practitioners
- Support the management of drug cost
- Identify opportunities to work one-on-one with beneficiaries regarding their medication therapy, if applicable
- Monitor and continuously improve current QA and UM operations and help ensure that corrective action is taken by the appropriate department when necessary to promote process improvement including but not limited to Concurrent Drug

Utilization Review (cDUR), Retrospective Drug Utilization Review (rDUR) and Medication Error Identification and Reduction (MEIR) activities

- Define and report appropriate measurement standards for UM activities
- Analyze various metrics to help ensure beneficiaries are receiving quality prescription drug coverage and services- Help ensure that QA and UM activities meet accreditation and regulatory requirements
- Maintain beneficiary, practitioner and client confidentiality in compliance with the Health Insurance Portability and Accountability Act (HIPAA)

SCOPE

The scope of the Clinical QA and UM Program addresses at a high level clinical functions that helps ensure beneficiaries receive access to high quality prescription drug coverage and quality service. Aspects of this may include, but not limited to, formulary management, cDUR, rDUR, clinical programs related to drug management, clinical complaints, prior authorization criteria development, appeals process, medication safety and MEIR.

PROGRAM STRUCTURE

The QA and UM Program Description is reviewed, revised and approved annually by the appropriate committee and/or the Chief Medical Officer or designee. The effectiveness of the Program is measured throughout the year by review of metrics and related activities.

CLINICAL QUALITY OVERSIGHT

Medicare Part D Clinical Quality Committee

This committee provides clinical oversight to the Medicare Part D program. The committee provides oversight of applicable policies and procedures to help ensure compliance to regulations while working with the business areas to close any identified gaps. The committee tracks performance measures related to Medicare Part D clinical programs.

The committee membership is a multidisciplinary group representing various departments that are responsible for providing services supporting Medicare Part D. The committee will meet at least quarterly and will maintain written records of these meetings and will report to the Chief Medical Officer and/or designated committee.

Oversight of other areas such as medication error tracking and formulary management are under the scope of other committees.

PERFORMANCE MEASURES

Tracking specific performance measures helps CVS Caremark Part D Services, LLC ensure the beneficiaries are receiving the highest quality prescription coverage and services. Performance

measures are tracked by the various business areas and through appropriate committees. If goals are not met and/or rates are trending negatively, actions are taken to improve performance.

Areas of performance measures reported as Book of Business (Medicare Part D) that fall under the scope of the Medicare Part D Clinical Quality Committee and/or the Clinical Quality Committee include but not limited to the following:

- § Clinical complaints
- § Prior Authorization
 - Turnaround times
 - Percentage approved
 - cDUR rates and trends
 - rDUR rates and trends
- § Appeals
 - Turnaround times
 - Volume by type
- § Medication Error Rates
- § Clinical outcomes associated with Medication Therapy Management Programs
 - Total population under management
 - Number of beneficiaries eligible for program
 - Number of interventions performed
 - Number of physician consults
 - Number of potential successes
 - Number of successes
 - Number of newsletters sent to beneficiaries
- § Patterns of inappropriate and medically unnecessary medication use
- § Satisfaction linked to UM and clinical care
- § Timeliness of new drug to market – Medicare Part D
- § Clinical measures related to the Medicare Part D population
- § Safety and Monitoring Solution
 - Total population under management
 - Number of profiles reviewed by R.Ph
 - Number of beneficiaries targeted
 - Number of letters sent
 - Case referrals

CLINICAL COMPLAINTS

Grievances related to quality of care issues, regardless of how the grievance is filed, are responded to in writing. The response will include a description of the beneficiary's right to file a written complaint with the Quality Improvement Organization (QIO) in the beneficiary's state of residence.

MEDICATION ERROR IDENTIFICATION AND REDUCTION (MEIR)

A Medication Error Identification and Reduction (MEIR) system is in place to identify and report errors within the mail service and specialty pharmacies. The system takes into consideration the internal control systems, current monitoring program and what is ultimately in the best interest of the beneficiary in preventing medication errors. Per CMS, a medication error is a preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient or consumer.

For the mail service and specialty pharmacies, these events are classified as Level One Dispensing Errors:

- § Incorrect Drug
- § Incorrect Patient or Patient Name
- § Incorrect Instructions/Directions
- § Incorrect Strength
- § Inappropriate Override of Drug Utilization Review (DUR) Alert

For the retail pharmacy, dispensing incident or Quality Related Event is defined as the incorrect dispensing of a prescribed medication that is received by a beneficiary. These events are classified as:

- § Incorrect Drug
- § Incorrect Strength
- § Incorrect Directions
- § Incorrect Patient Name on prescription label
- § Dispensed Prescription to Incorrect Patient
- § Dispensing Expired Medication
- § Drug Utilization Review (DUR)

The quality measures associated with MEIR are reported to the appropriate business area and/or quality oversight committee. Opportunities for improvement are identified and resources made available to work on these initiatives.

UM CRITERIA DEVELOPMENT AND MAINTENANCE

Drug utilization management services include the development and maintenance of Prior Authorization (PA), Quantity Limits and Step Therapy criteria for utilization by the Medicare Part D plan sponsors. The standard PA, Quantity Limits and Step Therapies include targeted drugs and objective utilization criteria to help enhance safe, evidence-based, clinically appropriate drug use.

The criteria for each drug are updated, reviewed and approved annually by Medical Affairs and the Clinical Services Operations Department, and undergo external clinical review by appropriate, actively practicing external physicians and pharmacists with current knowledge relevant to the criteria. The UM criteria are based on current principles and processes of pharmacotherapy, such as those included in drug labeling approved by the U.S. Food and

Drug Administration (FDA) and those published in CMS-recognized compendia.

Medicare Part D plan sponsors may adopt the standard PA, Quantity Limits or Step Therapies for their drug UM programs. Criteria may be customized by the client as desired. The client selects the drugs that UM programs will be applied to, subject to their plan design. In addition, the client approves (or modifies) and accepts all selected UM criteria.

PRIOR AUTHORIZATION

Prior Authorization is available as a stand-alone service to clients. It may also be provided in conjunction with Quantity Limits or Step Therapy protocols when a beneficiary fails to meet the requirements of that protocol. Claims for drugs subject to PA are screened at the point-of service, and the dispensing pharmacy is advised to have the prescribing practitioner contact the PA Department. The PA Department obtains the relevant information from the practitioner necessary to determine whether the beneficiary meets the established criteria for the requested drug. If the request is approved, an override is entered into the claims payment system. If the request is denied, the following information is provided to the prescribing practitioner and the beneficiary in writing:

- § The principal reason(s) for denial, in easily understandable language
- § A reference to the benefit provision on which the denial decision is based
- § A statement that the beneficiary and/or practitioner may request a copy of the actual criteria on which the denial decision was based and any other information relevant to the denial decision
- § Information regarding the right to appoint a representative to file a redetermination on the enrollee's behalf
- § For coverage denials, a description of both the standard and expedited redetermination processes and time frames, including conditions for obtaining an expedited reconsideration, and the rest of the appeals process; and
- § For payment denials, a description of the standard redetermination process and time frames, and the rest of the appeals process

Prescribing practitioners are provided with the opportunity to discuss any UM denial decision with a physician or pharmacist reviewer by contacting the PA Department.

QUANTITY LIMITS

Quantity Limits establish a maximum quantity of certain medications that will be covered by the Medicare Part D plan sponsor over a specified time period. The limit may be expressed in terms of quantity dispensed. When a beneficiary's claim exceeds the established limit for the drug, the claim will be rejected by the claims adjudication system. Messaging is provided to the dispensing pharmacy advising that the plan's quantity limit has been exceeded or that PA is required for coverage of additional medication quantities.

STEP THERAPY

The Step Therapy protocols may require that alternative drugs must be tried first and for certain durations before the prescribed drug will be covered. A PA/Exceptions process is available when the protocol is not satisfied, to allow therapy inconsistent with the protocol to be covered under appropriate clinical circumstances. The Medicare Part D plan sponsor approves and accepts all selected Step Therapy protocols and post-Step Therapy/PA criteria for the plan.

COVERAGE DETERMINATION

A Coverage Determination is any determination made by the Medicare Part D plan sponsor or their delegated entity with respect to providing or paying for a Medicare Part D drug. This includes the decision to not pay because the drug is not on the plan's formulary; because the drug is determined not to be medically necessary; because the drug is furnished by an out-of network pharmacy; or because the plan sponsor determines that the drug is otherwise excluded under section 1862(a) of the Act. This includes decisions concerning formulary and tiering exceptions, cost sharing for a drug and whether an enrollee has satisfied the PA or other UM requirements.

Standard turnaround times for coverage determinations are consistent with the regulations as provided by CMS and are reviewed by Clinical Services and reported to clients as required.

- § Expedited coverage determinations – within 24 hours after the plan receives the request for an expedited coverage determination
- § Standard coverage determinations – within 72 hours after the plan receives the request for a standard coverage determination

If a Medicare Part D plan sponsor does not provide notice of a coverage determination within the required timeframe, the plan sponsor must forward the complete case file to the Independent Review Entity (IRE) within 24 hours of the expiration of the adjudication time frame.

A review of the Medicare Part D beneficiary's coverage determination is completed and decisions are either approved or denied. If an override is required, it is entered into the system within 24 hours for an expedited coverage determination and 72 hours for standard requests. (This is calculated from the time of receipt of the request and the prescribing practitioner's supporting documentation.) The override will be effective at least through the end of the plan year if authorized by the prescriber and will not require another exception for refills. In addition, beneficiaries and their prescribing practitioner will be notified of the outcome of the coverage determination within 24 hours of receipt of the request and the prescribing practitioner's supporting statement for expedited requests and 72 hours for standard requests.

TIERING AND FORMULARY EXCEPTIONS

The tiering and formulary exception process is for Medicare Part D beneficiaries seeking to obtain coverage of non-formulary drugs or formulary drugs at a different tier.

- § Tiering Exceptions is a coverage determination decision made that will allow for coverage of a non-preferred drug at the preferred price whenever the Medicare Part D Plan Sponsor determines that the drug is medically necessary, consistent with the Medicare Part D beneficiary's physician's statement.
- § A Formulary Exception is a coverage determination decision that allows for coverage of a non-formulary drug at the formulary price whenever the Medicare Part D Plan Sponsor determines that the drug is medically necessary, consistent with the Medicare Part D beneficiary's physician's statement

Exceptions will not be made for drugs that do not meet the definition of a Medicare Part D drug.

REDETERMINATION

A redetermination is a review of an adverse coverage determination by CVS Caremark Part D Services, LLC; the evidence and findings, upon which it is based; and any other evidence the requestor submits or the Medicare Part D plan sponsor obtains. A Medicare Part D beneficiary may request a redetermination of an adverse coverage determination by submitting a request within 60 days of receiving notice of an adverse determination. If the 60-day period has expired, the beneficiary may request a redetermination and extension of timeframe in writing stating why the request was not filed on time with the Medicare Part D plan sponsor. If the beneficiary can show there was good cause for the delay, the extension may be granted. The requestor may withdraw a request in writing.

CVS Caremark Part D Services, LLC accepts redeterminations in writing, fax or orally in the case of an expedited request. Expedited requests are completed within 72 hours of receipt of the request. Standard requests are completed within seven (7) calendar days of receipt of the request. Beneficiaries and prescribing practitioners will be notified in writing of the determination outcome.

The redetermination process includes the following:

- § A review of the beneficiary's coverage determination
- § Collecting eligibility data, beneficiary demographics and pertinent clinical information
- § Reviewing additional evidence that may have been submitted by the beneficiary and/or the prescribing practitioner
- § Review process conducted by a person not involved in the original coverage determination
- § If the redetermination involved a denial based on lack of medical necessity, these are forwarded to an Independent Review Organization (IRO) for review by a practitioner with expertise in the field of medicine appropriate for the services under review. These would include formulary/tiering exceptions which were denied at the initial coverage determination level and reviews of PA denials
- § Following review, the decision is either an approval or denial
- § If approved, overrides are entered into the adjudication system within 72 hours for expedited and seven (7) calendar days for standard requests

Notification for expedited requests will be completed as expeditiously as the beneficiary's health condition requires but no later than 72 hours of the receipt of the request. Notification for standard requests will be completed as expeditiously as the beneficiary's health condition requires but no later than seven (7) calendar days of the receipt of the request.

If a Medicare Part D plan sponsor does not provide notice of a redetermination within the required timeframe, it must forward the complete case file to the IRO within 24 hours of the expiration of the adjudication timeframe.

INDEPENDENT REVIEW ORGANIZATION

Clinical redetermination reviews result from denials of PA or Formulary or Tiering Exceptions by which an adverse determination has been made that the requested medication is not within the prescribed CVS Caremark Part D Services, LLC standards. The Clinical redetermination review is performed by an IRO reviewer adhering to CMS definition of a Medicare Part D drug. A prescription drug is a Medicare Part D drug only if it is prescribed for a medically accepted indications defined as uses which are approved by the FDA or supported by a citation included in one of the three compendia listed below. These are:

- § American Hospital Formulary Service Drug Information
- § United States Pharmacopeia Drug Information
- § DRUGDEX Information System

A random sample of reviews conducted by the IRO is evaluated for quality and turnaround time adherence each month and reported quarterly to the Clinical Quality Committee. In addition, periodical teleconferences occur with representatives from CVS Caremark and the IRO to review the results of the quality review. The review includes:

- § Turnaround times (TAT) – Clinical redeterminations will be returned by the fifth calendar day after receipt by the IRO if non urgent and within 36 hours if urgent appeal. TATs are measured from the date/time that review is stamped received by the IRO until date/time the review is stamped by CVS Caremark
- § Redetermination review quality – Redetermination reviews for adherence to the predetermined indicators listed above.

CVS Caremark may request the IRO to submit a written corrective action plan, as needed.

ADDITIONAL LEVELS OF REVIEW

Reconsideration by the Independent Review Entity (IRE)

In cases where a beneficiary has filed a reconsideration request with the IRE, the IRE requests a copy of the case file and all of its contents by fax and it is provided to the IRE by fax within 24 hours for expedited requests or 48 hours for standard requests. The case file will contain all of

the information required under Chapter 18 of the Prescription Drug Benefit Manual section 70.30. The IRE notifies CVS Caremark Part D Services, LLC of their decision and if approved an override is entered for the timeframe as indicated by the IRE.

Administrative Law Judge (ALJ) and Medicare Appeals Council (MAC) Review

In cases where the amount in controversy meets the appropriate threshold requirement, a beneficiary who is dissatisfied with the IRE's reconsideration decision has a right to a hearing before an ALJ. A beneficiary who is dissatisfied with an ALJ hearing decision may request a MAC review. Upon notification of an ALJ hearing or MAC review, the Appeals Department will review the entire appeal history and determine whether there is a need for CVS Caremark Part D Services, LLC, on behalf of the Medicare Part D client that has selected such service, to file additional materials or attend the hearing. The plan, according to 42 CFR S 423.612 (a), is not considered a party to the ALJ hearing, but may participate in the hearing at the discretion of the ALJ. The Appeals Department will forward copies of all received materials to the applicable Medicare Part D client. The client will also advise the Medicare Part D Plan Sponsor to notify CVS Caremark Part D Services, LLC if they wish CVS Caremark Part D Services, LLC to take any action.

The Appeals Department will send a notification to the ALJ hearing officer/MAC representative regarding CVS Caremark Part D Services, LLC's decision to file documents, appear or take no further action. A copy of this notification will be provided to the Medicare Part D Plan Sponsor. Copies of all materials filed will be sent the client. The ALJ or MAC notifies CVS Caremark Part D Services, LLC of their decision and if favorable, an override is entered in the system within the applicable timeframe.

MEDICATION THERAPY MANAGEMENT PROGRAM

Medication Therapy Management Program (MTMP) monitors for appropriate medication usage. The MTMP is available as a stand-alone service to clients. The MTMP is designed to optimize therapeutic outcomes for targeted Medicare Part D beneficiaries by improving medication use and reducing adverse drug events. The MTMP identifies Medicare Part D beneficiaries at risk for adverse medical events and works collaboratively with prescribing practitioners and case managers to reduce that risk and avoid potential medical costs. The program encourages compliance with national evidence-based clinical guidelines. The MTMP identifies eligible beneficiaries using CMS targeting criteria, suggests prescribing practitioner interventions, provides Medicare Part D beneficiary education and includes CMS reporting requirements.

The MTMP is targeted at Medicare Part D beneficiaries taking more than eight (8) chronic Medicare Part D covered medications, who have three (3) or more chronic health conditions and who are likely to spend more than \$3,000 on covered Medicare Part D medications in identified years. The targeted chronic health conditions include the following:

- Alzheimer's Disease
- Asthma
- Behavioral Health (including depression, bipolar disorder and schizophrenia)

- Diabetes
- Cardiovascular Disease (including dyslipidemia, dysrhythmias, ischemic heart disease and hypertension)
- Heart Failure
- Osteoporosis

CORE SAFETY AND MONITORING SOLUTION

The Core Safety and Monitoring Solution is available as a stand-alone service to Medicare Part D Sponsors. The Core Safety and Monitoring Solution focuses on high-risk drug classes, such as controlled substances (CSs), by using indicators that suggest inappropriate use or misuse of CSs such as poly-pharmacy, “provider shopping” and high total controlled substance claims volume. Algorithms with a graduated risk score identify highest-risk plan beneficiaries and profiles are generated. On a quarterly basis, clinical pharmacists evaluate controlled substances claims and any available supporting medical data to identify potential medication misuse and inappropriate claims for appropriate intervention. After analyzing the generated profiles, clinical pharmacists may contact prescribing practitioners to obtain more clinical data regarding the beneficiary’s prescription use. If it is observed that there are potential misuse or safety concerns, letters are sent to the prescribing practitioner(s) noting the observation and requesting verification of drugs prescribed along with medical diagnosis codes.

The Core Safety and Monitoring Solution is offered and intended to complement a Medicare Part D Plan Sponsors’ general program management initiatives and can be included as one component of the plan sponsors requirements under Chapter 9 of the Prescription Drug Benefit Manual relating to fraud, waste and abuse.

ENHANCED SAFETY AND MONITORING SOLUTION

The Enhanced Safety and Monitoring Solution provides a more extensive range of interventions for those cases not successfully managed through the core Safety and Monitoring Solution. Cases are referred to the Enhanced Safety and Monitoring Solution – FWA program for SSIC or Clinical Operations for Medicare Part D Plan Sponsors – for further review by the Enhanced Safety Monitoring Review Committee. This review includes a secondary level of analysis and risk stratification that can culminate in one of the following two outcomes:

- Inclusion of the beneficiary in the beneficiary/practitioner lettering campaign. This is a three-letter campaign designed to promote awareness of the medication history to both the beneficiary and each practitioner who has written a prescription with the overall goal to change beneficiary behavior in line with current pain management guidelines;
- Referral of the case to one of the CMS Medicare Drug Integrity Contractors (MEDICs) for further investigation or to client for their reporting if deemed appropriate.

This program is available to Medicare Part D Plan Sponsors and can be purchased as part of the suite of services.

ACCESS

The following communication services to beneficiaries and practitioners:

- Access to staff at least eight (8) hours a day during normal business hours for inbound calls regarding UM issues
- Staff that can receive inbound communications regarding UM issues after business hours
- Staff that can send outbound communications regarding UM inquires during normal business hours, unless otherwise agreed upon
- Staff members that identify themselves by name, title and organization name when initiating or returning calls regarding UM issues
- A toll-free number of staff who accept collect calls regarding UM issues, and
- Access to staff for callers with questions about the UM process.

For urgent requests, the answering service relays contact information for the prescribing practitioner to an on-call pharmacist. The pharmacist will attempt to contact the practitioner within 24 hours to process the urgent request. For non-urgent requests, the prescribing practitioner may leave a voicemail that will be returned the next business day.

SAFETY

Mechanisms are in place to respond on an urgent basis to situations that pose an immediate threat to the health and safety of beneficiaries.

Drug Safety Alert

Key safety information is provided to beneficiaries and prescribing practitioners in the event there is a black box warning, recall or voluntary drug recall from the market, consistent with FDA, NCQA and URAC requirements. FDA defines the following categories:

Class I recall as a situation in which there is a reasonable probability that the use of or exposure to a product will cause serious adverse health consequences or death.

Class II recall as a situation in which use of, or exposure to a product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote.

Class III recall as a situation in which use of, or exposure to a product is not likely to cause adverse health consequences.

Market withdrawal as a firm's removal or correction of a distributed product that involves a minor violation which would not be subject to legal action by the FDA.

FDA defined classes of recalls (i.e., Wholesale, Retail and Patient level) are centrally processed and recorded for products stocked in CVS Caremark Mail Service Pharmacy and Specialty Pharmacy locations. In addition, CVS Caremark closely monitors safety alert Web sites for information on product irregularities, including fraudulent drug, to quickly respond by requesting verification of purchasing, requesting product "holds" or "inspections" in CVS Caremark Mail Service Pharmacy locations and creating proactive communication for clients and beneficiaries.

Another safety program available to clients is the use of electronic prescribing which allows the prescriber to:

- Send legible, printed prescriptions using reliable drug and formulary information
- Review drug-to-drug interactions
- Build and maintain a database of beneficiaries' prescription histories
- Review a beneficiary's complete medication history
- See only available strengths when selecting a medication
- Check plan-level formulary status for medicines and supplies
- Check beneficiary specific formulary status

Retrospective Safety Review Program

Retrospective Safety Review acts as a safety net for serious drug interactions. This retrospective DUR solution reviews both mail service and retail prescriptions 24-72 hours after the claim adjudicates for potential serious drug-drug interaction issues not addressed at point-of-dispensing. A communication is sent to the prescriber outlining the drug interaction and includes a complete beneficiary prescription profile.

DRUG UTILIZATION REVIEW (DUR)

Concurrent Drug Utilization Review (cDUR)

Point-of-Service DUR (cDUR) is a concurrent online editing system that electronically screens drug claims for several types of potential adverse drug interactions before each prescription is dispensed to a beneficiary and is operational for Medicare Part D plan sponsors supported by CVS Caremark Part D Services, LLC. These messages include:

- Excessive doses
- Therapeutic appropriateness
- Generic use
- Duplicate therapy
- Drug-drug or drug-allergy interactions
- Drug dosage
- Duration of treatment
- Clinical abuse or misuse
- Drug-disease contraindications
- Over and under utilization
- Drug-age precautions
- Drug-gender interactions
- Benefit design
- Regulatory limitations

When potential safety issues are triggered, warning messages are transmitted to the dispensing pharmacy to provide an opportunity for the pharmacist to evaluate the issues and determine the need for intervention.

Each processed prescription, whether mail or retail, that receives a cDUR warning based on information stored in First DataBank® and Medi-Span®, is reviewed by a pharmacist to make certain that the prescribed medication(s) is/are being properly administered to the beneficiary.

The cDUR enables the pharmacist to review the prescription, evaluate the warning for clinical relevance and significance and determine the next course of action. The following actions are available:

- The pharmacist determines that the cDUR warning is not clinically significant and requires no further intervention. The pharmacist documents any comments that are necessary in the prescription record and overrides the cDUR warning.
- The pharmacist determines that the cDUR warning is clinically significant and therefore requires a prescribing practitioner contact. The pharmacist routes the prescription to the appropriate area with question(s)/concern(s) documented in the prescription record.

The prescribing practitioner is consulted to verify if he/she is aware of the cDUR warning and the pharmacist documents one of the following outcomes:

- Prescriber agrees that the warning/interaction is clinically significant and requests that the prescription in question is cancelled
- Prescriber agrees that the warning/interaction is clinically significant and prescribes an alternate medication or dosing
- Prescriber is aware of the warning/interaction, but believes that the benefit outweighs the risks and still wants the prescription filled. The discussion with the prescriber will be documented in the prescription record and the cDUR will be overridden
- Prescriber is aware of the warning/interaction, but believes that the benefit outweighs the risks. However, the pharmacist disagrees and informs the prescriber that the prescription will not be filled. The pharmacist documents the discussion with the prescriber in the prescription record and the prescription is returned to the beneficiary with the appropriate general communication as to why the prescription was not filled

Retrospective Drug Utilization Review (rDUR)

Retrospective Drug Utilization Review (rDUR) provides a focused beneficiary-specific review of a particular drug, therapeutic drug class or issue. The review identifies potential opportunities for improvements in beneficiaries' therapies or practitioners' prescribing practices within the therapeutic class. Written communications are provided to prescribing practitioners that offer potential alternative therapies.

The Drug Savings Review program is an rDUR program that evaluates the appropriateness of therapy from a variety of perspectives, with a primary focus on ensuring safety and efficacy and a secondary focus on reducing unnecessary cost. Clinical pharmacists review flagged profiles

based on product selection, dosage, quantity and duration. Pharmacists review the clinical appropriateness of proposed interventions and avoid unnecessary communications with prescribing practitioners. All proposed changes are carefully researched. These letters contain specific clinical references from established medical literature and include supporting material. Prescribing practitioner responses to the alert letters are encouraged, but not required, and tracked when received. No changes are made to a prescription without the permission of the prescribing practitioner. By providing prescribing practitioners with specific and detailed clinical information, and specific suggested adjustments, prescribing practitioner can make informed, clinically-sound decisions with the health and well-being of the beneficiary in mind. The result is lower drug spending and appropriate utilization. All Drug Savings Review interventions are updated at least annually and are reviewed by independent external practicing physicians.

FORMULARY MANAGEMENT SERVICES

Formulary management services are provided, upon request, for Medicare Part D plan sponsors. The Medicare formulary template is developed and maintained according to the guidelines for formularies as published by CMS. The formularies developed by CVS Caremark for utilization by CVS Caremark Part D Services, LLC and its clients' Medicare Part D plans are based on current, accepted standards of medical practice and pharmacotherapy. A drug must be listed on the CVS Caremark National Formulary in order to be listed on the CVS Caremark Part D Services, LLC formulary. CVS Caremark formularies, including those used by CVS Caremark Part D Services, LLC and its clients' Medicare Part D plans, are reviewed and approved by the CVS Caremark National Pharmacy and Therapeutics (P&T) Committee. The CVS Caremark Part D Services, LLC formulary is submitted and approved by CMS.

Sources used to develop CVS Caremark formularies (including those used by CVS Caremark Part D Services, LLC and its clients' Medicare Part D plans) may include:

- Drug labeling approved by the FDA
- Published peer-reviewed journals
- Recognized compendia
- Accepted practice guidelines
- National Institutes of Health (NIH)
- Agency for Healthcare Research and Quality (AHRQ)
- Relevant government agencies, medical associations and national commissions

Formulary Review Committee

The Formulary Review Committee (FRC) provides recommendations for formulary management including requests for drug list additions and deletions. The FRC also provides recommendations for services that include the preparation and maintenance of formulary templates and tiered copay templates. The recommendations for drug list changes (i.e., additions and deletions) by FRC are reviewed and approved by the P&T Committee prior to implementation.

Pharmacy and Therapeutics Committee

The P&T Committee helps ensure the integrity of CVS Caremark Part D Services, LLC Formulary by impartially evaluating the clinical information regarding drugs presented for consideration for inclusion on the drug list. CVS Caremark utilizes the services of an independent P&T Committee to approve safe and clinically effective drug therapies. The P&T Committee consists of external clinical experts from a variety of medical specialties including high volume specialty physicians, pharmacists and other health care professionals. A majority of the P&T Committee members are actively practicing pharmacists and physicians. At least one P&T Committee practicing pharmacist and one practicing physician is an expert in care of the elderly or disabled persons. CVS Caremark employees with significant clinical expertise are invited to meet with the P&T Committee, but no CVS Caremark employee may vote on issues before the P&T Committee. Voting members of the P&T Committee may not be employees of CVS Caremark and must disclose any financial relationship or conflicts of interest with any pharmaceutical manufacturers.

Medicare Part D Drug Formulary/CVS Caremark Part D Services, LLC Formulary

At the request of CVS Caremark Part D Services, LLC, the P&T Committee reviews and approves a Medicare Part D Formulary. The Medicare Part D Formulary is a comprehensive list of prescription drugs across multiple therapeutic categories, which have been reviewed and approved by the P&T Committee based on their safety, efficacy and CMS requirements. Additions and deletions to the Medicare Part D Formulary must be reviewed and approved by the P&T Committee for clinical appropriateness. For example, such changes are made as new drugs are developed and subsequently approved by the FDA, as FDA approved indications are modified, as new clinical data becomes available or as new generic drugs become available in the marketplace. In addition, the P&T Committee reviews drugs within 90 days post launch and makes a decision on formulary status 180 days post launch. This may be escalated to 90 days for formulary decisions for drugs in classes of clinical concern.

The P&T Committee thoroughly reviews each individual drug for safety and clinical efficacy before adding the drug to the Medicare Part D Formulary. Clinical decisions are based on scientific evidence, standards of practice, peer reviewed medical literature, accepted clinical practice guidelines, as well as other sources of appropriate information, such as pharmaco-economic studies. A drug must be FDA-approved (or exempt from FDA approval) to be considered for inclusion. The P&T Committee does not consider the specific cost of a drug in determining the composition of the Medicare Part D Formulary. The P&T Committee also does not have access to, nor does it take into consideration, any information regarding rebates or negotiated discounts with pharmaceutical manufacturers by CVS Caremark, or the net cost of the drug after application of all discounts in deciding whether a drug is included or excluded from the Medicare Part D Formulary or any drug lists. However, the P&T Committee does consider drug utilization information in order to evaluate beneficiary disruption.

Oversight of Clinical Programs

CVS Caremark Part D Services, LLC offers several clinical programs which are designed to help improve clinical outcomes and/or reduce clients' overall drug or total health care spend. The

P&T Committee provides clinical oversight and guidance for all CVS Caremark Part D Services, LLC and CVS Caremark administered clinical programs by reviewing formulary management practices and policies associated with the following:

- Step Therapy
- Quantity Limits
- Prior Authorization Criteria

DELEGATION

Various functions may be delegated, which are mutually agreed upon and outlined in formal delegation agreements and/or incorporated into client contracts. Written delegation agreements outline the responsibilities of CVS Caremark Part D Services, LLC and the client, performance expectations and actions in the event of performance deficiencies. The delegation agreements delineate the reporting schedules and oversight expectations. CVS Caremark Part D Services, LLC works with Medicare Part D plan sponsors to provide information that may include, but is not limited to, applicable policies and procedures and reports. CVS Caremark Part D Services, LLC may accept delegation for applicable NCQA and/or URAC standards related to UM, Member Connections and/or Disease Management.

In some situations, the organization enters into a sub-delegation relationship. In these situations, a signed delegation agreement exists between the sub-delegated entity(s) and CVS Caremark Part D Services, LLC. This agreement calls for adherence by the sub-delegated entity to CVS Caremark Part D Services, LLC's standards of performance and outlines sanctions if those standards are not met. CVS Caremark Part D Services, LLC receives performance reports at predetermined intervals and monitors these at the quality committee level and internal operations. CVS Caremark Part D Services, LLC maintains ultimate responsibility for any activities that have been sub-delegated in accordance with client contracts and/or delegation agreements.

CONFIDENTIALITY, PRIVACY AND SECURITY PROCEDURES

Privacy policies and procedures have been developed and implemented to help ensure compliance with the HIPAA Privacy Rule. These policies and procedures help ensure that protected health information (PHI) is used and disclosed only in accordance with applicable law, and is appropriately safeguarded and protected from unauthorized access and disclosure. These policies and procedures specify that PHI may be used and disclosed only for the purposes of providing health care services, including treatment, payment and health care operations (e.g., UM, health management and case management), and as otherwise permitted by the Privacy Rule and other applicable law. In the case of information held by CVS Caremark Part D Services in its capacity as a business associate, the policies and procedures specify that the information may be used and disclosed only as specifically permitted by the business associate agreement.

All Medicare Part D employees are required to take annual HIPAA, privacy and security training. The training reviews all privacy and security policies, including the review of the

sanctions policy and procedure for disciplining those workforce members who violate the established policies and procedures or applicable law. The level of sanction depends on the seriousness of the offense but may extend to termination and/or criminal prosecution for the most serious violations.

STAFF TRAINING

Colleagues receive orientation/training related to their job function. For new colleagues, this occurs prior to assuming their assigned roles and responsibilities. Ongoing training is also required to maintain a specific level of performance and to meet annual requirements. Areas of orientation and training include:

- Explanation of departmental policies and procedures
- Navigation and use of the available computer system(s)
- Clinical decision support tools as appropriate
- Customer service objectives of the department
- HIPAA privacy policies and procedures and other applicable compliance standards
- Mandated Medicare Fraud, Waste and Abuse Training
- Confidentiality
- Conflict of interest
- Accreditation and regulatory requirements related to job function
- On-the-job training, sitting beside a trainer
- Overview of various clients and client specific procedures if applicable
- Review of medical terms used on the criteria forms including definitions and correct pronunciations, if applicable
- Ongoing education and training to maintain professional competency, if applicable

UTILIZATION MANAGEMENT STAFF RESPONSIBILITIES

Staffing requirements are reviewed at least annually in order to maintain business objectives and customer service goals. Staffing requirements take into consideration regulatory standards and productivity levels that will support both customer service needs as well as the cost-effective use of personnel resources. Staff licensure is verified upon hire by the Human Resources Department and licensure for the Prior Authorization staff is tracked for expiration yearly in the Prior Authorization Department database. A copy of applicable licensure or certification is kept on file.

Job descriptions are developed for each staff position that clearly identifies the scope of individual responsibility and authority. Also included in the job descriptions are the essential tasks, education, skill and experience requirements, and reporting relationships. The following are key positions linked with the UM Program:

Senior Vice President, Medical Affairs

- Serves as the primary physician officer and senior clinical spokesperson for the Medical Affairs department

- Develops and supports the strategic plan for the Company, particularly as it relates to clinical quality management, formulary development, external regulatory issues and managed care interests
- Provides clinical oversight and leadership in the development and implementation of clinical programs, products and interventions
- Acts as a liaison to external advisory groups, including the P&T Committee
- Reports to the Executive Vice President, Chief Medical Officer

Vice President, Medical Affairs, Pharmacy and Therapeutics Committee Formulary

- Provides coordination of the CVS Caremark Pharmacy & Therapeutics Committee process, including preparation and dissemination of meeting minutes
- Acts as a clinical expert for issues related to formulary management
- Provides coordination of clinical program oversight for the CVS Caremark clinical programs
- Reports to the Senior Vice President, Medical Affairs

Manager, Utilization Management, Clinical Development

- Manages the development, research and maintenance of UM criteria for standard and client-specific UM programs
- Interfaces with Clinical Service Operations, Account Management and Medical Affairs departments to implement clinical UM programs
- Analyzes program experience to provide continuous quality improvement of UM programs
- Reports to the Director, Clinical Services Operations

Director, Clinical Services, Prior Authorization

- Directs the operational activities of the Clinical PA Team
- Interfaces with Clinical Development, Account Management and Medical Affairs Departments to implement clinical programs into the claims adjudication system
- Reports to the Vice President, Clinical Services Operations

Manager, Prior Authorization

- Oversees the PA Team Supervisor, Pharmacists, Technicians and Call Center Representatives
- Helps ensure the compliance of prior authorization decisions with UM criteria, applicable policies and client contract provisions
- Investigates problems, irregularities, policy violations and incidents and implements appropriate corrective action and follow-up when necessary
- Reports to the Director, Utilization Management Operations