



# Pharmacy Manual

Version 22.2

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## Chapter 1 INTRODUCTION AND GENERAL INFORMATION

### Introduction to WellDyne

For 25 years, WellDyne has leveraged our clinical expertise to drive improved health outcomes for our clients and members. Now, we have scaled our business, added a deep commitment to innovation and are prepared to challenge the status quo in this industry. We are on a quest to fill the gap that exists today for PBM (Pharmacy Benefit Management) options serving the middle market. We offer the lowest net-cost solutions, highest-touch customer service and best-possible clinical results.

Our momentum is unstoppable — we have grown to partner with nearly 2,000 clients; serve more than 2.5 million members; built the capacity to fulfill more than 15 million prescriptions per year; and established a wholly-owned, award-winning specialty pharmacy. And still, we will not settle.

#### Behind the Name

**“WellDyne” represents our passion and our purpose.**

Our work has deeper meaning than simply managing prescriptions, which is why our name stands for more than who we are.



“Well” is what we do, in every aspect of our work — promoting improved health for our members and positive results for our clients.



“Dyne” is how we do it — through boundary-pushing ideas, dynamic technologies and solutions that evolve to meet real people’s needs.



WellDyne is a vigilant agent of change and a positive force for health and wellbeing.

WellDyneRx, LLC (“WellDyne”) appreciates your participation in its pharmacy network and your role in delivering quality pharmacy services to our members. This manual is intended to assist your pharmacy staff in processing prescription claims. WellDyne utilizes advanced technology to manage a network of more than 65,000 retail Pharmacies nationwide. Through state-of-the-art system design, plan benefits and eligibility are verified, claims are processed, and pharmacy benefits are administered for millions of plan members.

Participating pharmacy shall comply with the content within this pharmacy manual as it supplements and is incorporated into the Pharmacy Participation Agreement. The manual includes requirements to participate in WellDyne’s pharmacy benefit management, compliance, and other programs. Please visit our website to access the most recent published version of the pharmacy manual.

## Definitions

### **340B**

A program where drug manufacturers provide outpatient drugs to eligible health care organizations and covered entities at significantly reduced prices.

### **Accumulators**

Deductible/Out of pocket (OOP)/Benefit Max (Ben Max)

A running total of out-of-pocket money paid towards covered prescriptions.

### **AWP (Average Wholesale Price)**

The average wholesale price of a product as reported by Medi-Span or other nationally recognized source.

### **BIN – Bank Identification Number**

One identifier that is used for routing and processing prescription claims. The combination of BIN/PCN/Group ID or B/P/G is submitted by the pharmacy identifies the payor associated with the claim.

### **CMS – Centers for Medicare and Medicaid Services**

Government healthcare agency that administers Medicare program and partners with state governments to administer Medicaid.

### **COB – Coordination of Benefits**

The sequence of coverage when someone has multiple benefit coverage plans.

Example: Cardholder being covered on spouses plan also. Cardholder plan is primary coverage and spouse would be secondary coverage.

### **Cost Sharing**

Copayment, coinsurance, deductible, or other payment a member is required to pay for a covered product using the member's plan specifications.

### **Credentialing**

Network participation requirement, which is the process of obtaining, verifying, and assessing the qualifications of a pharmacy to provide services for an organization. Credentials are documented evidence of licensure, education, training, experience, or other qualifications.

### **DEA – Drug Enforcement Agency**

United States federal law enforcement agency under the U.S. Department of Justice, tasked with combating drug traffic and distribution within the United States.

### **Dispensing fee**

A fee that is paid to the pharmacy in addition to the calculated reimbursement for medications dispensed to patients.

**DUR - Drug Utilization Review**

Review of prescribing, dispensing, administering, and the ingestion of medications for patient safety.

**ERA – Electronic Remittance Advise (835 Files)**

Electronic detailed claim report that accompanies pharmacy reimbursement.

**ERISA – Employee Retirement Income Security Act**

A federal law that sets minimum standards for most voluntarily established retirement and health plans in the private industry to provide protection for individuals in these plans.

**FWA – Fraud, Waste and Abuse**

The overutilization of services or other practices that directly or indirectly result in unnecessary costs.

**GPI – Generic Product Identifier**

A 14-digit ingredient hierarchy numbering system used by Medi-Span that identifies medications from their therapeutic use down to the unique ingredient and strength regardless of manufacturer or package size.

**HHS – United States Department of Health and Human Services**

**HIPAA – Health Insurance Portability and Accountability Act of 1996**

As well as regulations implementing the act, as amended from time to time, including by the Health Information Technology for Economic and Clinical Health (HITECH) Act.

**HITECH – Health Information Technology for Economic and Clinical Health Act**

**IHS – Indian Health Services**

**LD or LDD – Limited Distribution or Limited Distribution Drug**

Medications that are available from a limited number of pharmacies based on distribution criteria, product characteristics, patient education, etc.

**Legend Medication**

A medication that bears a legend prohibiting the sale to the public with a prescription from a medical doctor or a licensed healthcare practitioner.

**LTC – Long Term Care**

Long Term Care pharmacy are pharmacies who service skilled nursing facilities that require extra provisions with unit dispensing packaging for ease in single dose dispensing and monitoring to the patient.

**MAC – Maximum Allowed Cost**

Maximum allowed cost set by WellDyne for a generic drug or other multisource product.

**Medi-Span**

A company that provides pharmaceutical information to healthcare professionals by maintaining a master drug database which includes current and comprehensive data from a single source.

**Medi-Span Drug Indicators M, N, O, Y**

Medi-Span's drug identifiers are used for medication classification and pricing.

M = Multisource Brand

N = Single source Brand

O = Brand that has a generic available

Y = Generic medication

**NCPDP – National Council for Prescription Drug Programs**

An organization whose purpose is to standardize the exchange of health care information and prescription claim processing.

**NDC – National Drug Code (seen as ##### - ##### - ##)**

An 11-digit number which identifies a medication. The first 5 digits identifies the labeler code associated with the manufacturer assigned by the FDA, the next 4 digits identifies the specific drug which is assigned by the manufacturer and the last 2 digits identifies the package size of the medication also assigned by the manufacturer.

**NPI (National Provider Identifier)**

A standardized 10 digit number used to identify an individual provider or health care entity.

**OIG and LEIE – Office of Inspector General's List of Excluded Individuals and Entities**

Government data base that is updated monthly to include a current list of excluded individuals or entities from participating in Medicare and Medicaid or other Federal health care programs due to misconduct of some sort.

**OTC (Over the Counter)**

Medications the public does not need a prescription to obtain.

**PCN – Processor Control Number**

The code entered by pharmacies in correlation with the BIN used for prescription claim processing to ensure the claim is routed properly for processing and payment. The combination of BIN/PCN/Group ID or B/P/G for correct routing of prescription claims.

**PHI (Protected Health Information) – Protected Health Information**

**PSAO – Pharmacy Services Administration Organization**

**U&C (Usual and Customary)**

The cost of a participating pharmacy's usual and customary (cash) price for a medication if the member did not possess pharmacy benefit coverage or discount card.

**WAC (Wholesale Acquisition Cost)**

The list price paid by a wholesaler, distributor and other direct accounts for medications purchased from the wholesaler's supplier.

## WellDyne General Information

### LOCATIONS AND CONTACT INFORMATION

|   |  |
|---|--|
| <b>WellDyne</b><br><b>P.O. Box 90369</b><br><b>Lakeland, FL 33804</b><br><b>Toll Free: 1-888-479-2000</b><br><b>TTY: 1-800-900-6570</b>   | <b>WellDyne</b><br><b>P.O. Box 4517</b><br><b>Englewood, CO 80155</b><br><b>Fax: 1-888-830-3608</b><br><a href="http://www.welldyne.com">www.welldyne.com</a>  |
| <b>Pharmacy Help Desk</b><br><b>Toll Free: 1-888-886-5822</b>   | Available 24/7/365<br>Fax: 1-888-830-3608  |
| <b>Prior Authorization</b><br><b>Toll Free: 1-866-240-2204</b>  | Fax: 1-888-473-7875  |
| <b>Network Administration</b><br><b>Toll Free: 1-866-813-3743</b><br><b>Email:</b><br><a href="mailto:RetailManager@netcardsystems.com">RetailManager@netcardsystems.com</a><br><b>For pharmacy network participation, contracting,</b> | <a href="http://www.welldyne.com/for-pharmacies">www.welldyne.com/for-pharmacies</a><br>Fax: 1-855-404-0968<br><a href="mailto:PharmacyInfo@welldyne.com">PharmacyInfo@welldyne.com</a><br>and payment set up and research |
| <b>Pharmacy Credentialing</b><br><b>Toll Free: 1-866-813-3743</b>   | Email: <a href="mailto:RxCredentials@welldynerx.com">RxCredentials@welldynerx.com</a><br>Fax: 1-855-404-0968   |
| <b>Pharmacy Audit</b><br><b>1-888-479-2000</b>  | Email: <a href="mailto:rxaudits@welldynerx.com">rxaudits@welldynerx.com</a><br>Fax: 1-855-618-4611   |
| <b>WellCard</b><br><b>Toll Free: 1-888-479-2000</b>   | Email: <a href="mailto:Discountcard@welldynerx.com">Discountcard@welldynerx.com</a><br><a href="http://www.wellcardrx.com">www.wellcardrx.com</a>  |
| <b>Compliance and FWA Reporting</b><br><b>ReportIT</b><br><b>Toll Free: 1-877-778-5463</b>  | Report Anonymously at <a href="http://www.reportit.net">www.reportit.net</a><br>Username: FWA TIPS<br>Password: FWA TIPS   |

WellDyne strives to ensure that pharmacy partners receive prompt and courteous attention when questions arise and uses several communication channels and points of reference for information. Pharmacy partners can count on our website for the latest version of the pharmacy manual, our payer sheets, bulletins, and Newsletters. For important business needs WellDyne will send emails, fax blasts, and provide point of sale communications. For additional assistance in processing a claim or questions concerning WellDyne pharmacy programs, **please contact WellDyne at the telephone number identified on the member's identification (ID) card** or contact the WellDyne help desk as indicated above. Hours of operation may vary during holidays or weekends.

## Chapter 2 PARTICIPATION

### Pharmacy Network Participation

WellDyne appreciates your participation in its pharmacy network and your role in delivering quality pharmacy covered prescription services to our participants.

#### Pharmacy Rights

- To be treated with respect and dignity
- To receive prompt and courteous responses to information requests
- To receive timely communications from WellDyne on issues affecting pharmacy services
- To receive reimbursement in a timely fashion for provision of covered pharmacy services
- To expect confidentiality of business, communications, and credentialing information
- A dispensing pharmacist is under no obligation to dispense a prescription, which, in his or her professional opinion, should not be dispensed.

#### Confidentiality

Pharmacy agrees to keep confidential and proprietary the following:

- Terms of the agreement and documentation related to the performance of the agreement, information relating to product formularies, pricing, including MAC pricing, Plan Sponsor information and any other information relating to WellDyne's business.
- Methods of doing business, including the operations of the National Pharmacy & Therapeutics Committee and WellDyne utilization review and quality assurance procedures and programs; and
- All symbols, logos, trademarks, trade names, patents, inventions, copyrights, copyrightable material, trade secrets, personnel information, operating manuals, memoranda, work marketing programs, plans and strategies, operating Agreements, financial information and strategies, and computer software and other computer- related materials developed or used in WellDyne business.
- To the extent a switch operator is accessing proprietary and/or confidential information of WellDyne or our clients, including utilization management criteria, network providers must restrict them from making any commercial use of this data.

### Pharmacy Service Responsibilities -Operations standards

As a pharmacy, you are responsible for monitoring and complying with all changes within the Pharmacy Manual. Failure to adhere to any of the provisions, as well as the terms of the agreement, which includes this Pharmacy Manual and all other applicable documents, will be viewed as a breach of the agreement.

- Nondiscrimination - Pharmacy understands and network participation requires that pharmacy and its staff, contractors or agents must not discriminate against an eligible member based on race, color, national origin, gender, age, religion, disability, medical conditions, sexual orientation, political convictions, and source of payment, marital or family status or any other basis prohibited by law. Unless professional judgement dictates otherwise, pharmacy must deliver pharmacy services to all eligible members. WellDyne reserves the right to terminate any pharmacy that does not adhere to this standard.

- Deliver pharmacy services with the highest quality standard of care by applying legal and professional judgement for the safety of our participants.
- Maintain minimum hours of operation of 20 hours per week to adequately serve the needs of WellDyne members.
- Adhere to patient confidentiality in accordance with HIPAA Privacy Rules
- Pharmacy must conduct business to meet all standards of operations with laws and government rules and regulations.
- Always maintain proper records and licensing applicable to federal, state, and local regulations for pharmacy and all pharmacy staff personnel.
- Conduct annual staff training on fraud, waste and abuse, HIPAA, anti-kickback laws, false claim rules and regulations
- Pharmacy personnel non-exclusion validation is regularly performed
- Comply with all credentialing and re-credentialing requirements and respond to requests with all supporting documents in a timely manner.
- Notify WellDyne in writing within 5 days of any event affecting legal status such as:
  - Pharmacy license/permit is limited, suspended, or revoked
  - Pharmacy receives notice of suspicion or investigation for violation of laws, rules or regulations related to practice standards, improper filling and labeling of prescriptions, HIPAA violation, diversion of controlled substances or disciplinary action due to fraud, waste, and abuse.
  - Any disciplinary action is taken against the pharmacy or any of its personnel for being an Ineligible Person according to the Board of Pharmacy, OIG, GSA, law enforcement or other regulatory agency.
  - Pharmacy receives a complaint or grievance from a member or individual, including a practitioner, acting on behalf of a member.
  - Suspects identity theft by an individual professing to be a member or acting for a member.
  - Suspects a member or a provider, including a practitioner, is engaged in activity that is conducive to fraud, waste, and abuse.
  - Pharmacy becomes non-compliant with the requirement to maintain liability insurance.
  - Pharmacy goes through Bankruptcy
- Maintain accurate pharmacy records such as patient profiles, original prescriptions, prescriber information, refill information, signature logs and wholesaler, manufacturer, or distributor invoices for a minimum of 10 years from the date of creation
- Ensure pharmacy equipment, location and operations are well kept with staff adherence to policies and procedures.
- Fill prescription orders as instructed by prescriber
- Submit medications found on the FDA NDC directory and must adhere and provide evidence to all requirements as outlined in Risk Evaluation and Mitigation Strategies (REMS) programs and defined by the Food and Drug Administration (FDA).
- Comply with the NCPDP standards for claim submission
- Adhere to all messaging and DUR alerts presented from processing system
- Ensure proper verification of every prescription order, prescriber, and member
- Perform proper consultation to members regarding medication being dispensed to ensure understanding of instructions, side effects, interactions, or storage requirements and timely notification if impacted by drug recall.
- Maintain signature log of member or representative who obtained medication in person or via off-site delivery.
- Collect member cost sharing amount communicated by NetCard Systems (WellDyne) claim processing system.

- Maintain adequate inventory for prescription fulfillment.
- Reverse claims within 14 days if not collected by participant or representative
- Pharmacy shall not refuse services to member due to financial concern or reimbursement dispute
- Cooperate, provide all requested documents, assist with compliance, and audit items.
- Maintain up to date and current with all pharmacy licensure, permits and/or certificates with NCPDP
- Notify NCPDP of any changes relating to pharmacy; including pharmacy closure, change in ownership, location, licensing, legalities, or privileges.
- Prompt notification of overpayment and return of overpayment within 60 days
- Pharmacy agrees to abide by the terms of the Pharmacy Manual and participate with WellDyne, clients and participants of WellDyne, to research and resolve network related issues (i.e., Claim reversal/resubmission requests, complaints, grievances and/or appeals from client or participants) in a timely manner
- Pharmacy's participation in a WellDyne or Client network shall not guarantee participation in all networks. WellDyne reserves the right to limit pharmacy's participation in a network
- Pharmacy understands WellDyne is relying on its participation in applicable networks and as such shall not be allowed to opt-out of any networks without the written consent of WellDyne unless the ability to opt-out is otherwise required by applicable law.
- WellDyne may participate with a plan sponsor under which the pharmacy's agreement with WellDyne will be used by such plan sponsor or its pharmacy claims processor on another adjudication platform. Pharmacy agrees to cooperate to support such arrangement.
- Pharmacy will refrain from advising any participant with plans utilizing WellDyne for any reason, including to improve compensation
- Pharmacy will refrain from advising, counseling, or soliciting any plans to terminate its relationship with WellDyne for any reason.
- Pharmacy shall not engage in any conduct or communication intended to discredit, defame, or disparage the quality of products or services associated with WellDyne or a client of WellDyne.
- Pharmacy shall not obtain clientele via cold-calling or unsolicited methods of obtaining a participant's billing information or offer to contact the participant's provider.
- All claims submitted by the pharmacy must be initiated by the participant or with the participant's authorization.
- Pharmacy shall not solicit a participant for mail delivery using UPS, USPS, Fed-Ex, etc., for any covered prescription services except upon the advance written approval by WellDyne

## Chapter 3 CONTRACTING AND CREDENTIALING

### Contracting

Pharmacy Network Participation is available to pharmacies that meet WellDyne's credentialing criteria. To initiate the credentialing and contracting process, pharmacies can complete a Pharmacy Network Participation Request Form found on [www.welldyne.com/for-pharmacies](http://www.welldyne.com/for-pharmacies) and submit using one of the following options.

- Fax: (855) 404-0968
- Email: [RetailManager@netcardsystems.com](mailto:RetailManager@netcardsystems.com) or [PharmacyInfo@welldyne.com](mailto:PharmacyInfo@welldyne.com)
- Mail: NetCard Systems at WellDyne  
P.O. Box 4517  
Englewood, CO 80155

For questions or additional information regarding WellDyne's contracting process, the Network Administration team can be contacted by phone. (866) 813-3743

Maintaining accurate and up to date pharmacy information with NCPDP is crucial to proper claims adjudication since NCPDP provides such data directly into the claims processing system used by WellDyne. Therefore, pharmacies are required to notify WellDyne of any changes in ownership, licensing, or location. WellDyne may deny or terminate participation in any or all networks for failing to maintain appropriate information with NCPDP.

### Contracting with PSAOs

PSAOs (Pharmacy Services Administrative Organization) are required to perform routine updates of the information regarding their affiliated pharmacy locations in the NCPDP database. This ensures all pharmacies attached to the PSAO are credentialed, contracted and NCPDP maintains complete/accurate information. WellDyne relies on the information in the NCPDP database and PSAO attests that the information in the NCPDP database is accurate. Actively removing an association of a non-contracted pharmacy from your PSAO does not meet the credentialing requirements set forth by WellDyne. PSAOs must remove such non-contracted pharmacy from affiliation in the NCPDP database. PSAO is also responsible for ensuring the integrity of any data and reconciling such information with NCPDP as required.

Pharmacies who engage a PSAO to handle contracting services shall refer to the PSAO for contract related inquiries.

### Contractual Mandates to Avoid

Members should be charged the applicable copay amount indicated on the online claim response only. The following actions, including but not limited in termination from the network:

1. Waiving the applicable Member Cost-Sharing Amount
2. Charging the Member more in Cost-Sharing Amount than provided by the POS System, including charging for non-covered ingredients

3. Pharmacy cannot collect the Part B cost share when a member is enrolled in an MAPD plan AND has Medicaid coverage.
4. Refusing to dispense a Covered Prescription Service, including Compounded Drugs, because of dispute over the reimbursement
5. Claim splitting or price rolling by submitting Compounded Drug Claims multiple times by changing the day supply/ quantity/U&C to circumvent PAs, or quantity limits, or dollar amount thresholds, or Benefit Plan limits, to obtain multiple dispensing fees or higher reimbursement

### OIG/GSA validations

Pharmacies are required to have a policy and procedure in place to confirm they do not employ or contract with any individual or entity which is excluded from participation in federal programs. Such verifications must be conducted upon hire or contracting of individuals or entities and at least monthly thereafter using the sources listed below. Pharmacies must certify all personnel have not been excluded from participation in any federal health care programs.

Department of Health and Human Services (HHS) ~ List of Excluded Individuals/Entities (LEIE) <https://oig.hhs.gov/exclusions/index.asp> or General Services Administration (GSA)

System for Award Management (SAM) ~ Excluded Parties Listing System (EPLS) LEIE and EPLS <https://sam.gov/content/exclusions>

If a pharmacy discovers an individual or entity is on the LEIE or EPLS as excluded or deemed ineligible, pharmacy must immediately notify of such individual or entity along with all exclusion information to WellDyne Network Administration at:

[RetailManager@netcardsystems.com](mailto:RetailManager@netcardsystems.com)

### Pharmacy Credentialing

#### Independent Credentialing and Re-credentialing

Professional credential verification and monitoring is required to participate in the WellDyne pharmacy network. Pharmacies must comply with WellDyne's credentialing and quality management initiatives by providing all necessary documentation and participate in re-credentialing activities to be compliant with applicable laws, rules and regulations, or accreditation standards. Minimum documentation required upon application to participate.

Independent Pharmacies Minimum Requirements:

- Completed Credentialing Application (Attachment B)
- Current valid copy of state Pharmacy License
- Current valid copy of DEA certificate
- No exclusion from internal verification of the Office of Inspector General (OIG) List of Excluded Individuals/Entities (LEIE), General Service Administration's (GSA) System for Award Management (SAM)
- Current Professional Liability Insurance with limits of \$1 million per claim or occurrence and \$3 million aggregate
- Photograph of dispensing area and pharmacy location store front

WellDyne has the right to determine whether a pharmacy meets or maintains the appropriate credentialing standards to serve WellDyne, its clients and benefit sponsors. Pharmacy must always maintain in good standing with all federal, state, and local licenses and/ or permits required by applicable law. WellDyne may request a copy of any document required for the credentialing of a pharmacy at any time after enrollment to the WellDyne pharmacy network and the appropriate documents must be provided within 48 hours of the request.

## PSAO Credentialing

Professional credential verification and monitoring is required for pharmacies who partner with a PSAO as well. PSAOs are required to sign an attestation stating they are responsible, perform, and maintain the necessary validations to ensure pharmacies meet the minimum credentialing requirements set forth in the participation agreement and provider manual listed below.

- Pharmacy has and maintains a current valid state Pharmacy License
- Pharmacy has and maintains a current valid DEA License
- Pharmacy has and maintains Professional Liability Insurance with limits of \$1 million per claim or occurrence and \$3 million aggregate
- No exclusion from internal verification of the Office of Inspector General (OIG) List of Excluded Individuals/Entities (LEIE), General Service Administration's (GSA) System for Award Management (SAM)

Annually, PASOs are required to:

- Provide their policies and procedures to credential their affiliated pharmacies
- Provide a complete listing of all their affiliated pharmacies
- Each pharmacy's State License number and expiration date
- Each pharmacy's DEA License and expiration date
- Current General Liability coverage policy
- Signed credentialing attestation

Understanding that even when affiliated with a PSAO, network participation is not guaranteed. Since WellDyne maintains multiple retail pharmacy networks and a need to alter a network, merge networks or move clients between networks, and agrees WellDyne may restrict, suspend, or terminate participation in one or more networks for business reasons, or as requested by a plan sponsor or governmental authority. WellDyne does not guarantee a minimum amount of business and may reduce, suspend, or terminate participation based on failure to comply with agreement held with PSAO, the Pharmacy Manual, based on behavior or practices that pose significant risk to the health, welfare, or safety of members, or promotes fraud and abuse, or is in violation of applicable laws, rules, and regulations. Credentialing and re-credentialing activities are deemed necessary by WellDyne for compliance with applicable laws, rules and regulations, or accreditation standards.

Additional Credentialing – Home Infusion Pharmacies with a PSAO affiliation  
PSAOs contracted with WellDyne for the Medicare Part D Home Infusion Pharmacy Network are required to ensure each pharmacy associated this network provides

infusion therapy services and meets the definition of a Home Infusion Pharmacy as defined by CMS and applicable CMS publications. If a pharmacy is a Home Infusion Pharmacy, it shall

- be capable of delivering home-infusion therapy in a form that can be administered in a clinically appropriate fashion
- be capable of furnishing infusion therapy for both short-term acute care and long-term chronic care conditions
- have professional services and ancillary supplies in place before providing home infusion therapies
- be able to provide home infusion therapy 7 day-a-week, 24 hour-a-day basis
- be accredited by an organization designated by CMS in 42 CFR part 486, Section 1861 in accordance with Section 1834

### Chain Pharmacy Credentialing

For a Chain Pharmacy to participate, the chain headquarters must submit a credentialing application, meet WellDyne credentialing requirements as specified in the credentialing application and be able to comply with the requirements stated in the Participation Agreement and in Provider Manual. All pharmacies shall be licensed pursuant to WellDyne's credentialing policy prior to submitting any claims.

WellDyne maintains the right to independently verify the credentials of any pharmacy, pharmacy owner, or pharmacist, included requesting credentialing documentation directly from the pharmacy as well as perform on-site visits to confirm credentials of pharmacy, pharmacist, or owner of pharmacy.

### Compound Credentialing

WellDyne requires pharmacies to meet additional credentialing prior to being allowed to process compounded drug claims. WellDyne will accept credentialing from a third-party entity, which is subject to change at WellDyne's sole discretion. Pharmacies will be required to meet and maintain all credentialing standards established by WellDyne and/or third-party accreditation entity such as PCAB, NABP or other accreditation entity.

Pharmacies must maintain compliance with all credentialing requirements and standards of practice set forth by WellDyne or the third-party entity. Failure to maintain compliance with this criterion may result in administrative action or termination of the agreement.

## Specialty Credentialing

Some clients or benefit plan sponsors may adopt a Specialty Credentialing Program for pharmacies participating in a WellDyne retail pharmacy network. Pharmacies must supply acceptable reference documentation to meet WellDyne's specialty pharmacy network requirements. If a pharmacy routinely dispenses specialty medications, the pharmacy should request credentialing materials from WellDyne. WellDyne may prohibit pharmacies who have not satisfied all requirements of the specialty credentialing process and have not executed a separate Specialty Addendum from processing claims for specialty medications. Obtaining specialty credentialing may not grant access to dispense specialty medications for all clients or benefit plan sponsors.

## Mail Delivery Pharmacy Additional Credentialing

Any pharmacy requesting mail order pharmacy network access must execute the Mail Order Pharmacy Network Agreement. Mail order pharmacy credentialing requires pharmacy licensing in all states to which the pharmacy will mail medications and agreement to the terms and conditions of the Mail Order Pharmacy Agreement. Pharmacies are required to be accredited with Verified Internet Pharmacy Practice Sites (VIPPS) as well as with URAC to meet credentialing requirements.

## Enhanced Credentialing

*WellDyne or its designee may perform an in-depth level of credentialing of pharmacies including on-site visits prior to or after contracting and participating in some of WellDyne's pharmacy networks, including Medicare Part D and Medicaid networks, therefore successful completion of enhanced credentialing may be a prerequisite in select CMS designated areas.* Enhanced credentialing applies to both directly and indirectly contracted pharmacy locations where pharmacies and if applicable, their PSAO agree to cooperate with WellDyne or its designee with the enhanced credentialing process as well as acknowledge non-cooperation or failing to pass the credentialing may result in denial, exclusion, or termination from network participation.

Pharmacies are required to provide a complete dispensing history, excluding PHI or payment information to the provider, for the requested period, which may include a period prior to being a contracted provider. Dispensing information shall include all prescription transactions regardless of association with WellDyne.

### *Additional state and plan requirements*

All pharmacy contracting may be subject to additional credentialing requirements to participate in certain plans or networks, including Medicare and Medicaid benefit plans. WellDyne reserves the right to require additional credentialing information from a pharmacy if applicable to participate in such a plan. Additional federal regulations apply to pharmacies, individuals or entities when working with Medicare and Medicaid benefit plans, therefore more frequent and stringent verification must be performed to ensure staff and new hire personnel is not excluded from a federal program.

### *340B program*

Pharmacies owned, operated or contracted with an eligible 340B Participating Entity to purchase outpatient Drug Products from drug manufacturers or wholesalers at reduced prices for use by eligible members under the Public Health Service Act, Section 340B program, pharmacy shall provide WellDyne with written notice of such eligibility. The parties acknowledge/agree WellDyne shall be entitled to modify the rates, fees, as well as other reimbursements in accordance with the pharmacy manual and/or agreement. Failure to notify WellDyne of its 340B eligibility status shall constitute a material breach of the agreement.

All claims submitted to 340B eligible members using 340B inventory, must utilize industry values as stated by the NCPDP Telecommunication Standards to identify 340B purchased drugs. All qualified 340B claims must include Submission Clarification code 20 along with identifier 08 for the Basis of Cost Determination when submitted to the WellDyne processing system.

## Chapter 4 CLAIM SUBMISSION AND RESPONSE

### Claim Submission



All participating pharmacies must comply with the Health Insurance Portability and Accountability Act (HIPAA), and the National Council for Prescription Drug Programs (NCPDP) transaction standards for pharmacy drug claims, coordination of benefits and related pharmacy services. Eligible members will receive an identification (ID) card containing pertinent processing information to help the pharmacy submit claims accurately and completely. In accordance with CMS requirements, and/or state regulatory requirements, a pharmacy provider must submit claims to the Medicare Part D sponsor or its intermediary whenever the ID card is presented or on file at the pharmacy, unless the member expressly requests otherwise. Pharmacies are required to submit all prescription claims electronically and in accordance with NCPDP D.0 Telecom Standards to obtain member eligibility, medication coverage and payment determination using the member's ID card.

### Downtime Procedure

In rare instances when pharmacy systems are not available due to issues outside of the pharmacy's control, the WellDyne pharmacy Help Desk is available to assist in these instances with confirming eligibility, verify coverage, copayment information, and the expected time the claims processing will resume. For these situations and once all information above is confirmed, we request that the pharmacy dispense necessary medications, collect applicable member pay amounts, and electronically resubmit claims when the system is available.

### Identification card

Information on ID cards may vary in appearance however, ID cards display essentially the same information; Member Name, Member Identification (ID), Rx Group Number, Processor Control Number (PCN), Bank Identification Number (BIN), along with important contact telephone numbers. Pharmacy is responsible for validating the authenticity of member's identity via government issued photo ID, in alignment with state dispensing requirements. Below is an example of WellDyne member ID card and please note ID cards may vary by payer.

|  |  |
|--|--|
| <br>Member ID: FAMILYID<br>Member Name: |  |
| RxBin: 008878  |  |
| RxPCN: WDRX  |  |
| RxGroup: RWITTEST  |  |
| This is an Rx Only Card.                |  |

|   |  |
|---|--|
| Contact Us:<br> Pharmacy Help Desk: 888-886-5822<br>Member Services: 888-479-2000<br>TTY: 800-900-6570 | Covered Dependents:  |
|  Mail Prescription Claims To:<br>WellDyne<br>P.O. Box 90399<br>Lakeland, FL 33804                      |  Website Information:<br><a href="http://www.WellDyne.com">www.WellDyne.com</a><br> |
| <br>This card is for information only and not a guarantee of benefits.                               |  |

## Requirements for Claim Submission

- Proper claim submission and routing of prescription claims requires
  - BIN #: 008878 (or as listed on ID card)
  - PCN # listed on ID card

Participant (Member) information found ID card is necessary for processing the prescription claim

- Member ID listed on ID card (ID length and requirement of person code, may vary by payer)
- Date of Birth
- Relationship code (1-Card holder, 2-Spouse, 3-Child, 4-Other)
- Group # listed on ID card

Pharmacy and Prescriber Identification Numbers

- Prescriber National Provider Identifier (NPI) field 411-DB, with qualifier 01 field 466-EZ
- Pharmacy National Provider Identifier (NPI) field 201-B1, with qualifier 01 field 202-B2
  - The unique 10-digit NPI assigned to health care providers such as prescribers and pharmacies, is used when submitting a HIPAA standard transaction and replaced legacy identifiers such as DEA and NCPDP numbers.

Please see [www.welldyne.com/for-pharmacies](http://www.welldyne.com/for-pharmacies) for WellDyne's payer sheets to find segment and field criteria required for processing prescription claims.

## Timely Filing and Claim Reversal Guidelines

Pharmacies shall submit complete and accurate information for all claims using the WellDyne claim processing system. For most plans' claims can be reversed up to thirty (30) days after the submission date. However, pharmacies are required to complete reversals within the same payment cycle as the submission or up to 14 days after claim adjudication for prescriptions that have not been obtained by the member. Failure to reverse claims may result in an audit and recovery of all costs associated with the claim. If you are unable to reverse a claim online, please contact the WellDyne help desk for assistance.

Please note that it is up to the discretion of individual plan sponsors or drug programs to impose tighter restrictions related to claim submission and reversal. See standard reversal guidelines below.

| <b>Days</b> | <b>Plan Sponsor</b>                |
|-------------|------------------------------------|
| <b>30</b>   | Commercial, Medicare LTC, Medicaid |
| <b>180</b>  | Medicare retail                    |
| <b>7</b>    | Discount Card Programs             |

### Travel or Early Refill Requests

Coverage for travel, lost, stolen, or forgotten medications varies by plan sponsor. These requests will be reviewed through the prior authorization process.

### Wholesaler, Manufacturer, and Distributor Product Validation

It is imperative for pharmacies to verify they are purchasing their inventory from a wholesaler, manufacturer, or a distributor for which all NDCs are properly registered with the FDA and from a licensed supplier to comply with the regulations of Good Manufacturing Practices (GMP) and Good Distribution Practice (GDP).

Wholesaler, manufacturer, and distributor invoices and other purchase invoices and documents must be accessible, maintained for a minimum of five years or as required by law or regulation and ten years in the case of Medicare Part D. These records substantiate that the drug products dispensed were purchased from an authorized source regulated by federal or state entities and NABP-VAWD (Verified –Accredited Wholesaler Distributors) and include valid licensure in the state the Drug Product is dispensed.

This validation of authenticity includes the purchase of legend and non-legend items (e.g., over-the-counter supplies) as well as DME products. Pharmacy must be able to document the source is authorized to include state or federal licensure, oversight by regulatory agencies to include the Food and Drug Administration (FDA) and DEA and ability to obtain pedigree information for purchased products.

### Drug Information Data Source

WellDyne uses drug information provided by Medi-Span for claim adjudication.

### Schedule II Controlled Medications

Federal and State regulatory agencies have implemented some regulations in effort to mitigate the opioid epidemic. This is an effort to support the Comprehensive Addiction and Recovery Act (CARA) for Schedule II controlled substances as it relates to partial/incremental fills which enacted the requirement of field Quantity Prescribed (460-ET) to be populated effective 9/21/2020. This represents incremental quantities of the total amount ordered which cannot exceed the total quantity prescribed and refills are not allowed for Schedule II prescriptions and pharmacies must comply with Federal and State rules and regulations when dispensing these medications. See Refill section for refill regulations on Schedule II-V and other federal legend drugs.

### National Drug Codes (NDC)

Pharmacies should always submit the eleven (11) digit NDC number of the actual package size of the drug product dispensed. Only the NDC of the actual drug product dispensed shall be submitted. Invoices and other drug transaction records shall also maintain the exact NDC number, as well as drug product name. Invoices, subject to audit at any time, as well as other drug transaction records submitted for medications that are not listed in the NDC Directory maintained by the U.S. Food and Drug Administration. WellDyne may deny or reverse claims using invalid NDC numbers or product names to recover amount paid as overpayments.

### Repackaged Products

Pharmacy shall not submit using an NDC that is identified as a repackaged drug. Repackaged NDC's are excluded from claim processing and must not be used at any time or in any way.

### Generic Substitution

Pharmacies agree to use the lowest priced generic version of a medication that has the same Generic Product Identifier (GPI) when filling prescriptions unless plan directs or state laws, rules and regulation instruct otherwise.

### Dispense as Written (DAW)/Product Selection Code – *Field 408-D8*

WellDyne follows NCPDP standards for “Dispense as Written” designation on prescriptions and monitors claims for appropriate DAW submission. Incorrect submitted DAW codes can impact pharmacy reimbursement as well as the cost share amount to the participant.

- 0 = No DAW: No DAW was indicated by either the prescriber or the patient.
- 1 = Physician DAW: Substitution Not Allowed by prescriber.
- 2 = Patient DAW: Substitution Allowed – patient requested product dispensed.
- 3 = Pharmacy DAW: The pharmacist selected the product.
- 4 = No Generic in Stock: There is not a generic available.
- 5 = Brand Dispensed Generic: A brand product was dispensed, but it was dispensed as a generic product.
- 6 = Override
- 7 = Substitution Not Allowed Brand Drug Mandated by Law
- 8 = Substitution Allowed Generic Not Available in Marketplace
- 9 = Substitution Allowed by Prescriber but Plan Requires Brand

For a brand name drug with a generic equivalent claim to be eligible to process using a DAW 1 designation, the prescriber must specify in writing or type “Brand Medically Necessary”. Preprinted prescription pads or prescriber simply indicating “DAW” does not qualify for DAW 1 claim processing which may be subject to audit and claim recovery. Only for prescriptions taken by telephone should “DAW” be used on original prescription; however clear documentation must accompany this stating that the pharmacist validated whether the prescriber or patient originated the request for the brand medication to be dispensed.

Pharmacies shall use DAW 2 when a participant requests a brand name drug to be filled when there is a generic equivalent available. Such requests must be clearly documented on the original prescription that participant acknowledged a generic equivalent was available, however requested brand name drug to be dispensed.

DAW code submission may change the calculation during claims adjudication. This is applicable for every DAW code excluding 5 and 7, however it may vary based on benefit plan sponsor. In addition, some plan sponsors may elect formularies where brand name products are preferred over generic equivalent options. Pharmacies should adhere to all formulary messaging returned by claim processing system by filling the prescription using the preferred formulary medication and appropriate DAW code unless directed otherwise by prescriber.

*Detailed Dispense as Written (DAW) guidelines:*

| <b>CODE</b> | <b>DESCRIPTION</b>  |
|-------------|---|
| <b>0</b>    | No Product Selection Indicated - This is the field default value used for prescriptions for single source brand, co-branded/co-licensed, or generic products. For a multisource branded product with available generic(s), DAW 0 is not appropriate and may impact reimbursement.   |
| <b>1</b>    | Substitution Not Allowed by Prescriber – This value is used when the prescriber indicates that the product is Medically Necessary to be Dispensed As Written. DAW 1 is based on prescriber instruction.   |
| <b>2</b>    | Substitution Allowed-Patient Requested Product Dispensed-This value is used when the prescriber has indicated that generic substitution is permitted. However, the patient requests the brand product. This situation can occur when the prescriber writes the prescription using either the brand or generic name and the product is available from multiple sources.                                |
| <b>3</b>    | Substitution Allowed-Pharmacist Selected Product Dispensed-This value is used when the prescriber has indicated that generic substitution is permitted. However, the pharmacist determines that the brand product should be dispensed. This can occur when the prescriber writes the prescription using either the brand or generic name and the product is available from multiple sources.          |
| <b>4</b>    | Substitution Allowed-Generic Drug Not in Stock-This value is used when the prescriber has indicated that generic substitution is permitted. However, the brand product is dispensed since a currently marketed generic is not stocked in the pharmacy. This situation exists due to the buying habits of the pharmacist, not because of the unavailability of the generic product in the marketplace. |
| <b>5</b>    | Substitution Allowed-Brand Drug Dispensed as a Generic-This value is used when the prescriber has indicated that generic substitution is permitted, and the pharmacist is utilizing the brand product as the generic entity.  |
| <b>6</b>    | Override-This value is used by various claims processors in very specific instances as defined by that claims' processor and/or its client(s).  |

|   |   |
|---|---|
| 7 | Substitution Not Allowed-Brand Drug Mandated by Law-This value is used when the prescriber has indicated that generic substitution is permitted but prevailing law or regulation prohibits the substitution of a brand product even though generic versions of the product may be available in the marketplace.   |
| 8 | Substitution Allowed-Generic Drug Not Available in Marketplace-This value is used when the prescriber has indicated that generic substitution is permitted and the brand product is dispensed since the generic is not currently manufactured, distributed, or is temporarily unavailable.  |
| 9 | Substitution Allowed by Prescriber but Plan Requests Brand - Patient's Plan Requested Brand Product to be Dispensed - This value is used when the prescriber has indicated that generic substitution is permitted, but the plan's formulary requests the brand product. This situation can occur when the prescriber writes the prescription using either the brand or generic name and the product is available from multiple sources. |

**Quantity**

Pharmacies must submit and dispense the quantity exactly as prescribed by practitioner on the prescription as allowed by State Law or up to the plan limitation. For proper reimbursement, the quantity dispensed must reflect the exact metric decimal quantity, without rounding. If the quantity to be dispensed is uncertain, pharmacies must contact the prescriber to determine the appropriate amount to dispense and document the amount on the original prescription.

Pharmacy should adhere to the following general rules for product packaging and quantities.

- Use the standard billing units listed below for the applicable medications
  - EA – each (tablets, capsules, patches, etc.)
    - Example: written for Lisinopril 30 tablets
      - > Quantity to submit = 30
    - Example: written for Lidocaine 30 patches
      - > Quantity to submit = 30
  - ML – milliliters (liquids such as suspensions, nasal sprays, eye drops, etc.)
    - Example: written Albuterol Neb solution 2.5mg/3ML #30
      - > Quantity to submit = 90
    - Example: Novolin-N U-100 1 vial
      - > Quantity to submit = 10
  - GM – grams (ointments, creams, inhalers, etc.)
    - Example: Proair HFA inhaler #1
      - > Quantity to submit = 8.5
    - Example: Androgel 1.62% 20.25/1.25gm #30
      - > Quantity to submit = 37.5
- Submit claims using the lowest ingredient cost dosage form or the lowest package size container available.

### Days' supply

Pharmacy is obligated to enter the correct days' supply of prescriptions for all claims submitted. Accurate days' supply should be based on the quantity required to meet the daily dose written by the provider and will be referenced for Drug Utilization Review (DUR) and refill allowance edits. The following are examples of appropriate day's supply submission:

- One (1) patch weekly is four (4) patches for a twenty-eight (28) days' supply.
- Two (2) tablets twice weekly is eight (8) tablets for a twenty-eight (28) days' supply.

A thirty (30) day supply is no longer standard; some programs permit extended day's supplies. Pharmacies should be mindful to use proper quantity and daily dosage prescribed to calculate accurate days' supply. Audits routinely identify discrepancies in days' supply, it is important to always transmit the accurate day's supply to receive the allowed day's' supply through the member's benefit plan.

### Dispensing limitations

There are some medications in the market where the smallest package size and duration of treatment exceeds standard plan days' supply allowed. Pharmacies shall submit the actual duration of treatment initially to see if the plan allows for the extended duration of treatment before contacting the help desk for an override or entering the incorrect days' supply for the treatment. If a claim submitted has a quantity representative of the smallest commercially available package size or represents a single course of therapy (e.g., Seasonique® as a ninety-one (91) day supply) and rejects, the pharmacy shall request an override through the Pharmacy Help Desk. The pharmacy must act appropriately to prevent early refills to avoid potential waste, audit, and reclamation of payment.

### Vague or Missing Directions on Prescriptions

If a prescription contains ambiguous directions "as directed" or "as needed" pharmacies are responsible for obtaining and documenting more detailed instructions so proper days' supply can be calculated. Clarified directions along with whom and what date the directions were provided, and pharmacist's initials, shall be clearly documented on the original prescription.

## Compound Prescriptions

Fulfillment of compounded medications must comply with all rules and regulations as designed by USP and good compounding practices. Compound medication claims are subject to audit and to full recovery for any claim found not in compliance with good compounding practices.

- WellDyne's standard compound program requires a compound to consist of two or more ingredients, one of which must be a legend drug that is weighed, measured, or mixed as directed by the prescriber.
- WellDyne requires pharmacies to follow highest industry standards using only approved ingredients of acceptable strength, quality, and purity with accurate labeling, packaging.
- All active ingredients must be covered by the participant's benefit plan. Any product excluded through the benefit plan will cause the compound claim to reject.
- Any prescription ingredient that is not approved by the FDA will not be eligible for reimbursement.
- Some compound medications may require prior authorization or plan sponsors may elect to exclude compounds as a covered benefit all together. However, if covered, these claims often are subject to cost coverage limitations, requiring clinical review and approval prior to payment being processed.

### Compound documentation and Quality Control log

Proper compound documentation or detailed recipe must be maintained along with the original prescription by pharmacy and should include the following information.

- Compounding log and quality control procedure to include,
  - Name, strength, and dosage form of the compound
  - Names, quantities, and product identification numbers with lot numbers of every ingredient used in the compound
  - Source and calculations of all ingredients used in the compound
  - Name, date, and time of who compounded the medication
  - Prescription number and expiration (or use by) date for the compound
  - Facility details and/or equipment required for the compound

### Processing Compound Prescriptions

- Multi Ingredient D.0 claims coding is required, use compound code '2' in NCPDP field 406-D6 when submitting compound claims.
- NCPDP compound segment must be submitted to include everything used in compounding the prescription.
  - Correct product identification number for every ingredient
  - Appropriate product identification qualifier for every ingredient
  - Accurate product quantity for every ingredient
  - Accurate cost for every ingredient
  - Correct basis of cost for every ingredient

### Compounded drug claims general exclusions

- Ingredients with missing or invalid NDC numbers are not eligible for reimbursement
- Reconstitution of an oral antibiotic or similar product
- Mixing of water or saline solution to another Federal Legend Drug
- Raw bulk chemicals from a non-FDA registered manufacturer facility and wholesaler with locations within the US
- Charges for ancillary supplies, flavoring/sweeteners, equipment depreciation and/or labor are not eligible for reimbursement
- Compounded Drugs for office use by medical providers and not compounded for individual WellDyne participants
- Repackaged NDC or drug products
- Imported or reimported drug products into the United States, including bulk powders utilized in the preparation of compounded medications

### Prescription origin code claim submission

To comply with NCPDP standards pharmacies must correctly submit the Prescription Origin Code.

Please submit one of the following data elements within Prescription Origin Code (419-DJ):

- 1 = Written
- 2 = Telephone
- 3 = Electronic
- 4 = Facsimile (Fax)
- 5 = Pharmacy transfer

Claims submitted missing one of these values will reject with the following NCPDP rejection code 33 — “RX ORIGIN CODE CANNOT BE “0” ON NEW CLM”.

If rejection occurs, please resubmit the claim with the appropriate value.

### Coordination of Benefits (COB)

Coordination of Benefits (COB) is the sequence of coverage when a participant has more than one prescription benefit coverage plan. WellDyne supports electronic COB claim processing per NCPDP standards, participant’s benefit plan and applicable regulations. Claims should be submitted using Other Coverage Codes (OCC) 1 through 8 and additional required COB information listed on WellDyne payer sheet within COB segment. Pharmacies are required to verify all benefit coverage prior to initiating any claim submission to ensure proper coverage sequence is applied.

### Subrogation and coordination of benefits (COB)

Subrogation as permitted under applicable law, WellDyne reserves the right to recover benefits paid for a participant's prescription services when covered by another third (3rd) party or if incorrect benefit plan was used for processing at the time when prescription services were received by participant.

### Retroactive eligibility changes

Eligibility under a Plan may change retroactively if:

1. Plan Sponsor or WellDyne receives information that an individual is no longer an eligible member under the plan.
2. Member's policy/benefit contract has been terminated.
3. Member decides not to purchase continuation coverage.
4. Eligibility information received by WellDyne is later updated; or
5. As determined by CMS, with respect to Medicaid, MA-PD, PDP, or another plan.

If a pharmacy has submitted claim(s) that are affected by a retroactive eligibility change, a claim adjustment may be necessary.

### Data accuracy

Entry of the Prescriber and Member information is paramount in being able to identify true occurrences of fraudulent and abusive practices, as well as reduction in waste associated with payment of Claims for excluded Prescribers. Pharmacy agrees to follow all federal and state requirements, including Medicare and Medicaid rules, accurate submissions and temporary supply rules which are mandated by many of these programs.

### Submission of the Pharmacy's Cash Price as the U&C Price

Every claim submitted to the NetCard Processing System is required to have the pharmacy's Usual and Customary (U&C) charge for the product being submitted. The U&C charge represents the cash price charged for a product that would be given under the same circumstances if the Member did not possess pharmacy benefit coverage or discount card. WellDyne acknowledges situations in which there is not a U&C charge applicable and will accept \$0.00 or recognize a blank value as \$0.00 for the U&C charge for claim submission.

Pharmacy shall collect from the member the amount received from the NetCard Systems Processing System using formula of lesser of the Copayment, Coinsurance, Deductible, U&C or Calculated Price. In instances where both the U&C price and the Calculated Price are lesser than plan designates for member responsibility amount, pharmacy shall accept the lesser amount as payment for the final cost of the prescription. Charging a member an amount greater than the U&C or retail price is prohibited and a violation of the agreement.

### Refill details

Refills are monitored by the number of days submitted on the claim. This value is based on the quantity and frequency stated on the prescription. All refills must be approved at the direction of an authorized prescriber and approved by participant prior to filling

unless pharmacy utilizes refill reminder programs where medications will be picked up by participant. Retail refill limitations may vary by plan sponsor however standard refill limits require 75% of the medication from the previous fill to be depleted to be eligible to refill the medication unless there has been a change in direction by the prescriber. DUR edit for early refill message will display if appropriate. Refill allowances listed below for prescription medications.

Legend Prescription Medication: Original fill + 11 refills within 365 days from the date on the original prescription

Controlled Medication, Schedule II: No refills allowed

Controlled Medication, Schedule III, IV, V: Original fill + 5 refills within 185 days from the date on the original prescription

## Programs

### Clinical (WellManaged) Programs

WellDyne provides several “WellManaged” programs and formulary options which are safe and effective while reducing prescription drug costs. Pharmacies are obligated to comply with the formulary program associated with the member’s plan and try to get the prescription changed if a non-formulary drug is prescribed.

*DUR Programs* WellDyne monitors drug utilization and prescribing practices associated with prescriptions processed for the safety of our members and to guard against therapeutic duplication, duplicate ingredient dispensing, drug-drug interactions and ensure proper dosing and adherence of drug products and improve therapeutic outcomes.

*Prior authorization (PA)* WellDyne’s Prior Authorization Program is used to optimize patient outcomes by ensuring that the most appropriate medication is being used while reducing waste, error, and unnecessary prescription drug use to keep prescription drug costs under control. Drug Products requiring prior authorization may require confirmation of diagnosis or submission of laboratory and other supporting documentation.

*WellManaged Generics* Step therapy program that promotes the use of safe, equally effective yet less expensive alternative drug product prior to ‘stepping up” to higher cost therapy options.

*Quantity limits (QL)* WellDyne’s Quantity Limit Program is used to ensure the prescribed quantities are consistent with clinical dosing guidelines and medical literature, and to provide safe and appropriate use of certain medications.

*WellManaged Opioids* program leverages morphine equivalency dose (MED) checks at the point-of-sale, prior to pharmacy dispensing, to ensure patients receiving higher doses are receiving appropriate prescriptions and being carefully monitored by their providers. The POS MED checks combine all opioids a patient is taking to calculate the total MED. Using advanced technology, patients who are prescribed potentially inappropriate concomitant medications with opioids are identified for both prescriber and patient outreach.

*WellAssist* program utilizes pharmaceutical manufacturer financial programs to reduce out of pocket costs at the point of sale. WellAssist focuses program savings on a variety of specialty and chronic condition medications which offer patient financial assistance.

### **Prior Authorization Review**

A Member, Member's appointed/authorized representative and/or a Prescriber may submit a request to initiate the PA review process. If Prior Authorization of a Drug Product is required, the Pharmacy must make good faith efforts to contact the Prescriber. Coverage determinations made through the PA review process will be based on Benefit Plan's approved criteria, clinical guidelines approved by the Pharmacy & Therapeutics Committee (PTC) or other professionally recognized standards of practice. If a Member's Drug Product has a PA, ST or QL restriction, the Member or Member's appointed/authorized representative should contact WellDyne customer service number located on the back of the Member's ID card. In addition, the Prescriber may contact the PA Department to start the prior authorization process by providing relevant, patient-specific clinical information to be reviewed by a licensed Pharmacist or medical director.

#### Prior authorization (PA) process key steps

- The Member's Prescriber or Member's appointed/authorized representative can submit a PA request.
- A pharmacy technician enters the information into our PA system and performs the initial request review.
- If the request falls outside the established guidelines, a pharmacist reviews the request and contacts the prescriber if additional information is required.
- If required by state law, the request will be reviewed by a medical director before issuing the final decision.
- Additionally, where required by law, the Prescriber is offered the opportunity for a peer-to-peer consultation prior to the issuance of an adverse medical necessity determination.
- Once the request is approved or denied, our PA system will automatically generate written correspondence to both the Member and Prescriber.
- The WellDyne complies with all State and Federal regulations for PA turnaround time. Our typical turnaround times are as follows:
- Non-urgent cases have a turnaround time of fifteen (15) days for commercial Benefit Plans, or seventy-two (72) hours for Medicare Benefit Plans from receipt of all information required to review the case.

Urgent cases have a turnaround time of seventy-two (72) hours for commercial Benefit Plans, from receipt of all information needed to review the case or twenty-four (24) hours for Medicare Benefit Plans from receipt of Prescriber supporting documentation.

## Vaccines

Pharmacy wishing to dispense and administer vaccines must have a Vaccine Amendment on file. WellDyne reserves the right to request documentation supporting this requirement and vaccine claims are subject to audit and recovery.

## Specialty Drugs

Specialty drugs are covered in a retail setting on a Plan Sponsor basis and may vary from group to group. Pharmacy wishing to provide specialty drugs at retail need to have a signed amendment on file and pass credentialing requirements as well.

## Claim Response:

### Collection of Members Cost-Sharing Amount

Pharmacy must charge the Member the Cost-Sharing Amount indicated in the online response and only this amount. Waiving the amount associated with the Member Cost-Sharing is prohibited, unless required by law (e.g., Qualified Medicare Beneficiary or other Qualifying Medicaid coverage) and is considered a material breach of the Agreement.

Pharmacy reimbursement pricing information, as well as prices paid to Pharmacy for individual Claims under the Agreement are confidential and proprietary WellDyne information and may not be disclosed on Member receipts or insurance profiles. The Pharmacy may print U&C price and Member pay amount on the receipts, as well as the insurance profiles.

Pharmacy agrees apart from (i) Cost-Sharing Amounts (ii) reasonable returned check costs and (iii) reasonable collection costs related to subparts (i) or (ii). Pharmacy shall not in any event, including, without limitation, non-funding by WellDyne or non-payment by a Client, insolvency of WellDyne or a Client, or breach of the Agreement, bill, charge, collect a deposit from, seek compensation, remuneration or reimbursement from, hold responsible, or otherwise have any recourse against any Member, or any other person (other than the applicable Client) acting on behalf of any Member, or attempt to do any of the foregoing for any Prescription provided to any Member pursuant to the Agreement. This section shall survive expiration or termination of the Agreement.

In accordance with U.S. Department of Health and Human Services, Health Resource Services Administration (“HRSA”) rules and requirements, Pharmacies owned by or contracted with a 340B Participating Entity may discount or waive the Cost-Sharing Amounts owed by Members for reasons of genuine financial need. In these situations, CMS rules and the Agreement allow 340B Participating Pharmacy to do the following:

After submitting the claims for Part D Covered Prescription Services for Medicare Part D Members via the NetCard processing system, 340B pharmacy may adjust, discount, or waive the Cost-Sharing Amount provided by the on-line POS System response per the guidance on genuine financial need as described by HRSA.

### Pharmaceutical manufacturers cost- share amount coupons

Pharmacy is responsible for ensuring pharmaceutical manufacturer copayment cards or coupons (i.e., “coupons”) are not utilized for claims under the Medicare Part D, other federally funded health programs, and any commercial or Medicaid Client Benefit Plan[s] that prohibits use of coupons to offset all or a portion of a Member’s Cost-Sharing Amount.

Pharmacies must include operational practices to require validation of each customer/Member that presents a copayment card coupon to assure that use of a coupon is not prohibited by the health program and/or Benefit Plan. Pharmacies accepting coupons in lieu of collecting the full cost-share amount in violation of the health program and/or Benefit Plan may be subject to audit, recovery and other administrative actions, up to and including termination from all WellDyne’s Pharmacy Networks.

### Processing and pricing; successful adjudication of a claim

The acceptance of a successfully adjudicated claim constitutes Pharmacy’s (i) acknowledgment of its participation in the applicable network and (ii) acceptance of all corresponding terms and conditions, including the rates and reimbursements of claims, for such network. In the event of a conflict between the pharmacy manual, Agreement, addendum, attachments, fee schedule, NetCard processing system reimbursement response or any other pricing arrangement, the NetCard processing system reimbursement response shall govern, unless an error resulting in overpayment occurs.

Claims submitted by Pharmacy for Members using an WellDyne network or Client network via the NetCard processing system for retail prescription benefit management or Claim processing are reimbursed at the lesser of the following: the Benefit Plan or network AWP discount or other referenced based pricing plus applicable dispensing fee; MAC (when applicable for Covered Prescription Services); Pharmacy’s Submitted Cost Amount; Pharmacy’s U&C which would be given under the same circumstances if the Member did not possess prescription benefit coverage; or the submitted ingredient cost. Pharmacy payments must be reconciled by Pharmacy (e.g., if Pharmacy receives a payment from WellDyne with incorrect NPI, NCPDP number, name, address, Prescriptions processed by Pharmacy or other key identifiers, Pharmacy must report the discrepancy via telephone and in writing, such as electronic or otherwise), to WellDyne within fourteen (14) days upon receipt. Determination of payment accuracy will occur by WellDyne within fourteen (14) days. In the event any payment has been sent to a Pharmacy in error, Pharmacy is subject to immediate offsets from future payments or is required to immediately reimburse WellDyne via a bank-drawn check or electronic fund transfer as directed by WellDyne. Knowledge or lack thereof, of overpayment provides no rights to the receiver (i.e., Pharmacy), all payments must be returned immediately as described above and interest at the greater rate of 1.5% per month of the total balance or required by law. Knowledge by Pharmacy of extended (greater than 30 days) overpayment may be subject to network termination, penalties, including, but not limited to court costs, collection agents, travel and attorney’s fees as required to recover the funds. If the Pharmacy is disputing the reimbursement, please see MAC appeals contact information provided in this Pharmacy Manual.

### Maximum allowable cost (MAC) pricing, review and appeals

To assure the MAC list accurately reflects market pricing and the availability of generic drugs, WellDyne utilizes multiple sources to determine MAC pricing. The sources include pricing available to purchase in the market from nationally recognized wholesalers such as Cardinal, Amerisource Bergen, and McKesson, Medi-Span Drug Database, CMS, and other published sources. These sources are monitored and updated at least every seven (7) calendar days to help manage market pricing fluctuations on the MAC list. WellDyne reserves the right to update its MAC pricing methodology and to use alternative, reputable sources at its discretion. Upon written request, as well as to the extent required by law, WellDyne will make available the current and applicable MAC price information to Pharmacy. Such MAC price lists constitute confidential information.

To comply with applicable state laws, WellDyne has implemented an appeal process to allow a participating network pharmacy to dispute MAC pricing of a covered prescription drug product. This process also includes a timely review and investigation to resolve MAC disputes. For a MAC Appeal, pharmacy must follow directions below within thirty (30) calendar days from the date of service submitted on the claim. Pharmacies contracted with a PSAO; MAC appeals may be submitted to the PSAO for processing.

#### MAC Appeals:

Download Appeal Form at <https://welldyne.com/for-pharmacies>

1. Please provide all accurate information on Required information tab
2. Email completed form to [RetailManager@netcardsystems.com](mailto:RetailManager@netcardsystems.com) with a title of MAC appeals
3. A response will be provided via email
4. If notified that the price has been adjusted, please reverse, and reprocess the claim

Network participation, credentialing, and reimbursement inquiries: (866) 813-3743  
Email address: [pharmacyinfo@welldyne.com](mailto:pharmacyinfo@welldyne.com)

Pharmacy Help Desk – for claim submission inquiries: (888) 886-5822

WellDyne shall investigate and resolve the appeal within ten (10) business days after the fully completed form is received. All MAC appeal review determinations on any individual claim from a pharmacy are final and will not be reviewed again. This section shall be considered a part of the Agreement with WellDyne (including all amendments, addenda, or Compensation Exhibits) to the extent the Pharmacy provides Covered Prescription Services to Members. The terms of this section shall be considered general information regarding MAC.

MAC appeal requests will be reviewed to determine the appropriateness of pricing utilized by WellDyne for reimbursement. WellDyne will utilize all available information to

deduce the appropriateness of reimbursement. Participating Pharmacy may be required to submit their actual acquisition cost (including any rebates) for each item being reviewed. When required, failure to submit the actual acquisition cost (including rebates) will not result in WellDyne rejecting Claims for review but could diminish the accuracy of review and therefore the likelihood of a successful and complete review.

Please access the MAC Appeal Submission Guide for instructions on processing appeals at the following link: <https://welldyne.com/for-pharmacies>

### MAC State-Specific

To the extent your Network Pharmacy Provider is located in a state requiring different time periods to submit or resolve MAC Appeals than noted above, please see the Appendix B.

WellDyne reviews appeals in accordance with state laws as applicable, which can vary based by line of business (e.g. Commercial, Medicare, Medicaid, etc.). In addition, if your pharmacy is located in one of the states listed in the Appendix B, the respective state provision(s) in Appendix B supplements or replaces that aspect of the WellDyne standard MAC Appeal process.

In addition to MAC Appeals, WellDyne does not prohibit Pharmacies from filing complaints with regulators for any and all other applicable issues, including the Department of Insurance. However, the Network Pharmacy Provider should first follow the Dispute Resolution Process described in the Pharmacy Network Agreement.

### Disputed claims

In the event a Pharmacy seeks to dispute a Claim due to alleged error, miscalculation, discrepancy, or non-compliance to terms specified in the Agreement or otherwise questions the accuracy of any Claim, the Pharmacy must notify WellDyne within one-hundred and twenty (120) days of the date of fill in writing.

Written outreach must include Pharmacy NCPCP number, Eligible Person ID number, Prescription number, date of fill and details such as why an adjustment is needed (e.g., wrong NDC submitted, wrong quantity submitted, etc.) Should the Pharmacy fail to contact WellDyne within the required response time, Pharmacy deems the accuracy of processing and payment of Claims, as set forth in that cycle. Overpayments made to the Pharmacy are not applicable. Pharmacy may only submit Claims to WellDyne for Drug Products properly labeled and dispensed in accordance with the Prescription order for the Drug Product.

### Resubmitting a claim

All Claims submitted via the POS System will result in a response Transaction message (e.g., Paid or Rejected). If Pharmacy has submitted a Claim via the POS System and Pharmacy does not receive any Claim response Transaction message via the POS System within a reasonable amount of time, Pharmacy should verify the accuracy of the submitted Claim and resubmit the Claim to WellDyne via the POS System.

### Transmission fees

Notwithstanding anything to the contrary in this Manual or the Agreement, transmission fees which may vary in amount will be incurred, subject to applicable regulatory requirements, by the Pharmacy per online Transaction. Fees are assessed to support Pharmacy payment, as well as reconciliation, Help Desk service, education regarding network compliance, transactional and billing processes, among other initiatives. However, excessive, or disruptive process inquiries, including, but not limited to non-contracted pharmacy status, duplicate payment and remittance requests, excessive Member/Pharmacy grievances, third-party biller intervention, incomplete or inaccurate credentialing submissions, contract non-compliance and/or failure of the Pharmacy to submit Claims through the WellDyne designated claim processor POS System, are subject to higher transmission fees.

## Chapter 5 PHARMACY PAYMENT AND REPORTING

### Pharmacy payments

Standard pharmacy payment cycle is twice a month and consists of claims processed from the 1<sup>st</sup> through the 15<sup>th</sup> and the 16<sup>th</sup> through the end of the month unless the pharmacy resides in a state which has non-standard pharmacy payment regulations. WellDyne reserves the right to make payment directly to a Pharmacy at its sole discretion. WellDyne, acting on behalf of Benefit Plan Sponsors, will process the Clean Claim for payment of each Covered Prescription Service dispensed to eligible members. WellDyne will reimburse pharmacy for each Clean Claim no later than thirty (30) calendar days after the completion of the payment cycle during which the claim was successfully processed, or a lesser time if required by applicable law or regulation, and contingent upon Client or Benefit Plan Sponsor funding.

If Pharmacy is affiliated with a third party contracting or purchasing group, the Pharmacy is subject to all terms and conditions of the written Agreement between WellDyne and the entity. All communication and inquiries regarding pharmacy payments should be directed through the third-party contracting entity or purchasing group.

### Payment rules under Medicare and Medicaid programs

In accordance with requirements as set forth in 42 C.F.R §423.520(a)-§423.520(h) Pharmacy Claims will be paid as follows:

- For Medicare Part D Plan Sponsor Clean Claims will be paid within fourteen (14) days after the date of receipt for electronic Claims and within thirty (30) days after receipt for paper Claims.
- For managed Medicaid, Clean Claims will be paid within thirty (30) days after the date of receipt for electronic Claims and within thirty (30) days after receipt for paper Claims, except where a state requires a shorter timeframe, in which case, state requirements prevail.

## Claims

- If the Claim is determined not to be a Clean Claim, WellDyne will notify the submitting Pharmacy. This notification will specify all defects or improprieties in the Claim and will list all additional information necessary for the proper processing, as well as payment of the Claim, if applicable.
- WellDyne will not provide notice of a new deficiency that could have been identified in the original Claim submission.
- Medicare Supplier Number — WellDyne encourages Pharmacy to obtain and maintain (for each Pharmacy location) a Medicare Part B supplier number pursuant to 42 CFR §424.57.
- Pharmacy agrees to inform WellDyne of the Medicare Part B supplier number assigned to each Pharmacy location for record-keeping purposes and Client Pharmacy Network directories.

Effective January 1, 2016, and to the extent required by 42 CFR § 423.505(i)(3)(vii), WellDyne will disclose all individual updated Drug Product prices to the applicable Pharmacy in advance of the use of such prices for reimbursement of applicable Claims if the source for any Prescription Drug Product pricing standard is not publicly available.

## Electronic remittance advice (ERA) 835 and electronic fund transfer (EFT)

Participating pharmacies have the option to receive electronic pharmacy payments via automated clearing house (ACH) or wire transfers in lieu of traditional paper checks. To receive electronic payments, WellDyne requires pharmacies to complete an ACH application document, provide a current bank letter of authorization as well as receive electronic remittances advice (835) reporting. Please contact Pharmacy Network Administration by email or phone below.

Phone:

(866) 813-3743

Email:

[pharmacyinfo@welldyne.com](mailto:pharmacyinfo@welldyne.com) or [retailmanager@netcardsystems.com](mailto:retailmanager@netcardsystems.com)

Non-compliant or non-participating pharmacies are not eligible to receive EFT/ACH payments. WellDyne will verify and validate every application received for electronic payment and reserves the right to deny pharmacy from receiving electronic payments for any reason of suspicion.

## Remittance

The option for remittance advice is delivered by mail in paper format. If you would like to receive electronic 835 remittances, please visit [www.welldyne.com/for-pharmacies](http://www.welldyne.com/for-pharmacies) to complete and print the 835-set-up form. The files are delivered via sftp and available for 7 days after every pay cycle. You can submit the completed form to [retailmanager@netcardsystems.com](mailto:retailmanager@netcardsystems.com) or fax to 1-855-404-0968.

## Chapter 6 COMPLIANCE, FWA AND AUDIT PROCESS

### Fraud, Waste and Abuse

A Pharmacy is required to report any suspected or potential FWA to WellDyne. WellDyne has a strict non-retaliation policy which protects those reporting any adverse action because of a good faith report. WellDyne actively investigates and refers, as appropriate, any FWA activity by Pharmacies, associates, Members, vendors, contractors and/or other business entities.

Pharmacy should initiate an investigation immediately, but no more than two (2) weeks from the date a potential compliance or fraud matter has been reported or identified. If, upon investigation, the Pharmacy believes a potential misconduct has occurred, the Pharmacy is required to report the alleged activity to the WellDyne without fear of retaliation.

A Pharmacy involved in providing services for Medicare Part D/Medicaid Members is responsible for implementing a program to control FWA and to facilitate compliance in the delivery of Covered Prescription Services through the Medicare/Medicaid benefits. If Pharmacies suspect any fraud and abuse by a member or Managed Care Organization (MCO), the Pharmacy must report this to the applicable federal/state agency.

In addition to the reporting requirements above, Pharmacies must cooperate and assist any federal/ state agency charged with the duty of identifying, investigating, sanctioning, or prosecuting suspected FWA. Pharmacies must provide original and/or copies of all information as requested by any such federal/ state agency, allow access to premises, as well as provide records to any federal/state government unit or investigating agency, upon request (i.e., free-of-charge).

### Common FWA schemes to avoid

Pharmacies should be aware there are common FWA schemes perpetrated by Prescribers and Members. The following is a list of FWA types which could be perpetrated by Prescribers. This is included for educational purposes only and is not an all-inclusive list and applies to commercial and governmental plans alike.

*Illegal remuneration schemes:* Prescriber or Member is offered, paid, solicited, or receives unlawful remuneration to induce or reward them for inappropriate behavior. Some examples of an illegal remuneration scheme include when a Prescriber receives something of value for writing Prescriptions for medically inappropriate or unnecessary drugs/ products or to induce the Prescriber to prescribe certain Drug Products rather than others, when a Pharmacy waives a Member's Cost-Sharing Amount to encourage their patronage, etc.

*Script mills:* Provider writes Prescriptions for Drug Products or Compounded Drugs that are not medically necessary, often in mass quantities, and often for patients that are not his others.

*Inappropriate relationships with health care provider:* Potentially inappropriate relationships between pharmaceutical manufacturers and Prescribers, such as “switching” arrangements to induce a Prescriber to switch the prescribed drug from a competing product; incentives offered to Prescriber to prescribe medically unnecessary drugs; consulting and advisory payments, payments for business courtesies and other gratuities, educational and research funding; improper entertainment or incentives offered by sales agents.

*Illegal usage of free samples:* Providing free samples to Prescribers knowing and expecting those Prescribers to bill federal health care programs for the samples. The following is a list of types of FWA which could be perpetrated by Members. This is included for educational purposes only and is not an all-inclusive list:

*Overutilization and drug-seeking members:* Member seeks, obtains, and uses a Drug Product even though the risk of harm exceeds the benefit.

*Altered and forged Prescriptions:* Member alters the quantity and/or strength on a valid Prescription or illegally creates Prescriptions using stolen or forged Prescription pads.

*Pharmacy hopping and doctor shopping:* Members visit numerous doctors to obtain Prescriptions for Prescription drugs and/or controlled substances and visit numerous Pharmacy to facilitate the filling of excessive quantities of Prescription drugs.

*Prescription diversion and inappropriate use:* Members obtain Covered Prescription Services from a Pharmacy and give or sell these as Drug Products to someone else. This can also include the inappropriate consumption or distribution of a Member’s Covered Prescription Services by a caregiver or anyone else.

*Resale of drugs on black market:* Member falsely reports loss or theft of drugs or feigns illness to obtain drugs for resale on the black market.

*Misrepresentation of status:* Member misrepresents personal information, such as identity, eligibility, or medical condition to illegally receive benefits including Medicare and Medicaid.

*Theft of prescriber identifiers:* Member steals DEA number, Prescription pad, or e-prescriber authentication (login) information for creating fabricated Prescriptions.

#### *Pharmacy FWA attestation*

Pharmacies are required to maintain proper policies/procedures related to the provision of training on Compliance and FWA. Compliance and FWA training are a critical component of Pharmacy operations and are required to be completed upon initial hire, as well as annually for all federal/state/locally funded Benefit Plans. CMS requires all MAOs, Medicare-Medicaid plans (MMPs), Medicare Part D plans (PDP), as well as

Medicare Part D Sponsors to require FWA and general compliance training from their FDR contracted entities, including but not limited to, WellDyne and Pharmacies. In addition, FDRs are required to monitor federal exclusions lists on at least a monthly basis and annually distribute code or standards of conduct information. State Medicaid agencies have made similar requirements of their Medicaid plans, including MME Plans.

Each year by December 31, Pharmacies are required to electronically sign the WellDyne FWA Online Attestation to satisfy mandatory compliance requirements related to guidance from CMS. CMS has set forth expressed guidance within the Federal Register at 42 CFR Parts 422 and 423 and other agency guidance requiring MA- PD, Medicare Part D Sponsor or their delegates, FDR entities to demonstrate compliance with the following:

Network Provider Pharmacy (participating in any of WellDyne's Medicare Part D networks) hereby verifies/ certifies it has completed satisfactory annual FWA and general compliance training programs provided by CMS; also, has provided staff with links to our Client(s) or Benefit Plan Sponsors Code of Conduct policies. In addition, Pharmacy hereby attests to not being excluded from participation in federal or state health care programs (e.g., Medicare and Medicaid) by checking their status in the exclusion lists maintained by the Office of Inspector General (OIG) U.S. Department of Health and Human Services (HHS) and U.S. General Services Administration (GSA) System for Award Management (SAM). Pharmacy has reviewed the OIG-HHS and GSA-SAM lists prior to hire/contracting and monthly thereafter for its current employees/contractors, health professionals or subcontracted delegates, working with Plan Sponsor programs to ensure none are excluded from participating in these programs.

This information is available at the following sites:

Office of Inspector General's (OIG) — U.S. Department of Health and Human Services (HHS) ~ List of Excluded Individuals/Entities (LEIE) — [oig.hhs.gov/exclusions/index.asp](http://oig.hhs.gov/exclusions/index.asp)  
General Services Administration (GSA) — System for Award Management (SAM) ~ Excluded Parties Listing System (EPLS) — [sam.gov/portal/SAM/#1](http://sam.gov/portal/SAM/#1)

Completing the annual CMS FWA and general compliance training, as well as the online attestation, is required by your WellDyne's Agreement(s) and is your obligation as a recipient of Medicare Part D or any other government funds. CMS does not require that FDR entities adopt Client(s) or Benefit Plan Sponsors Code of Conduct policies, but that these sponsors distribute Code of Conduct policies to FDR contracting entities for the purposes of supporting CMS FWA and general compliance requirements. As noted in the training materials, Pharmacy must complete the CMS provided and/or other industry accepted FWA & General Compliance training module. This training must be completed by all employees within ninety (90) days of hire/contract and annually thereafter.

### *Please Note:*

Beginning in 2016, use of the CMS training materials located on the provider portal is required and the content of these materials cannot be modified to ensure the integrity and completeness of the training.

A record of completion (e.g., certificates with passing scores, training log) of the required CMS compliance and FWA training by Pharmacies should be maintained for a period of ten (10) years and made available immediately upon request to WellDyne in case of an audit.

It is not necessary to submit a copy of your training passing score certificates or training log to WellDyne; however, Pharmacies are required to attest to the completion of annual training requirements.

Non-compliance with this provision may result in remedies such as corrective actions or termination from WellDyne's networks. Unless agreed to by WellDyne, a PSAO must comply by providing a single attestation on behalf of its entire membership of Pharmacies.

Should Pharmacies not have access to the Internet, please feel free to contact WellDyne Pharmacy Network Administration to obtain additional information on how to maintain compliance.

### **Cultural competency training**

Pharmacies are to be knowledgeable about cultural differences of our members, to promote the delivery of services in a manner which accounts for the diverse Member population, which is completely free of bias including, but not limited to, those with limited English proficiency, diverse cultural/ethnic backgrounds, and mental and physical disabilities. Additionally, providers must cultivate an environment free from discrimination based on gender, sexual orientation and/or gender identity. Pharmacies should be aware of any indications related to abuse, neglect, national origin, exploitation and report any concerns when warranted.

### **Pharmacy Audits**

#### *Types of Audits*

*On-Site Audits:* On-site audits provide an opportunity to review prescriptions orders and signature logs, assess adherence to laws pertaining to overall pharmacy operations and file information, controlled medications, and basic requirements. In addition to identifying fraud, waste, and abuse the audit will provide for Medicare Part D, adherence to CMS rules and regulations, general and state requirements for licenses, inventory management and appropriate pharmacy equipment.

*Desk Audits:* To complete a Desk audit, each pharmacy is contacted to provide copies of the original prescription order including the signature log of the claims to be reviewed. These audit options are a cost-efficient tool, serving as a less expensive means to identify waste, abuse, and recoverable overpayments as well to discover fraudulent providers warranting more in-depth auditing.

*Investigative Audits:* Based on the discovery of suspected fraud during an audit or feedback from WellDyne clients or members, there may be a requirement for a more thorough assessment. WellDyne or its contracted vendor may conduct a more comprehensive audit that includes an On-Site visit to investigate the pharmacy. This will include an analysis of all claims for the suspected pharmacy for a determined timeframe. In addition to reviewing claims, the auditors may also investigate a pharmacist's license sanctions, criminal records and background checks on staff, banking/financial information, and corporate ownership and ownership of other entities.

All Claims submitted to WellDyne are subject to audit. The WellDyne Pharmacy Audit Program helps to protect against FWA, ensure Claims are submitted and dispensed in accordance with WellDyne guidelines and the Pharmacy complies with those guidelines, as well as the terms/conditions for participation in the applicable network.

WellDyne or its authorized agent, governmental agencies or their representatives, (hereafter referred to as "Auditor"), shall have the right to audit Pharmacy during normal business hours, with reasonable notice of fourteen (14) days or more in compliance with all state laws to examine/audit the books, records, signature logs, files, equipment and their respective facilities of all Pharmacy transactions which relate to any aspect of the performance of the Agreement including the transactions contemplated under the PM or Plan Specifications, as well as requirements set forth by Law. If Auditors are denied access to requested audit documents, 100% of the amount previously paid for the Claim(s) in issue becomes due immediately. Audits will be conducted in accordance with applicable laws and state regulatory guidelines.

Pharmacy shall cooperate with Auditors and promptly provide access to all information or documents deemed necessary by Auditors. Auditors may reproduce any record at its own expense; however, no original copy may be removed from Pharmacy 's facilities. Auditors may report audit findings to WellDyne's Clients, appropriate governmental entities, regulatory agencies and professional review and audit organizations.

The parties agree all audits will be conducted in accordance with applicable laws and any additional required language to be included in the Agreement or Pharmacy Manual by such applicable laws shall be deemed included for the term of the Agreement and a period of five (5) years thereafter or in accordance with applicable law.

### *Audit purpose*

The purpose of the WellDyne policy is:

- To *validate* and photograph, if necessary, any or all the following:
- Accuracy of paid Claims, contractual compliance, regulatory compliance, various aspects of Drug Product inventories, presence of required signage and/or documentation; and/or
- To *observe* and photograph, if necessary, any and/or all the following:
- Overall facility operations and conditions; and/or
- To *monitor* for, *detect/prevent* FWA activities and/or transaction submission errors in the billing of Covered Prescription Services.

In-depth audits contain a larger number of transactions; include a comprehensive review of Prescriptions, as well as their supporting documentation, proofs of delivery, credentialing, licensure review, confirmation work and facility/ compliance reviews.

Audits may take the form of a phone call, on-site visit, internal Claims review (desktop audit), Client-directed/ regulatory investigative and/or compliance reviews. The Pharmacy will provide WellDyne, Auditors, or its designee, during normal business hours, access to examine, audit, scan and copy all records deemed by WellDyne or Auditor as necessary to determine compliance with the terms of the Agreement and the Pharmacy Manual. These audits are necessary for Clients or Benefit Plan Sponsors to comply with State and Federal requirements and Plan Specifications. Any discrepant Claims found during an audit will require reimbursement to WellDyne, other than claims submitted due to a clerical or other error where the patient has received the drug for which the claim was submitted.

Audit recoveries will be deducted from future remittances to Pharmacy. Should insufficient funds be available to offset such recoveries, Pharmacy will be responsible to submit payment within fifteen (15) days of demand for payment.

WellDyne routinely monitors online claim transaction data and conducts audits on a continuous basis. To conduct these audits, Pharmacies may be contacted by telephone, mail, fax, and/or email and are required to provide such records by the due date in a manner mutually agreeable by the parties, while always ensuring safe transmission of sensitive documentation.

### *Procedures for audit compliance*

In general, WellDyne will notify the Pharmacy with no less than (14) days' notice in advance of written notification of a pending in-depth audit involving Claims review. However, if WellDyne suspects that the Pharmacy has engaged in fraudulent activity, WellDyne or Auditor may conduct an on-site audit with no less than (14) days' notice. Should the Pharmacy refuse to allow WellDyne or Auditor access to the pharmacy facilities, WellDyne reserves the right to recover the full amount paid or due to the Pharmacy for any Claims subject to the audit and may terminate the Pharmacy for cause. WellDyne or its designee shall have the right, with no less than (14) days' notice, at reasonable times, to conduct a brief compliance check and a standard inventory shelf check.

As a Pharmacy, you are required to maintain Prescription records (including copies of Prescriptions and signature logs) in accordance with the Agreement, including the Pharmacy Manual, and with applicable state and federal regulations. WellDyne may request such records from the Pharmacy pursuant to a Client, Benefit Plan Sponsor, Government Authority or regulatory audit or inquiry. Pharmacy is required to assist WellDyne with the retrieval of such records in a timely manner to allow WellDyne to meet the deadlines as set forth by the Client, Benefit Plan Sponsor, Government Authority, or regulatory agency.

#### *On-site audits*

- Pharmacy will be contacted no less than (14) days prior to an on-site audit with written confirmation of date and an approximate time.
- Pharmacy must be staffed to assist in the audit and answer any questions, retrieve information required and facilitate an effective on-site audit.
- Pharmacy will provide Auditors a safe workspace with a sufficient work surface that is well-lit and clutter-free, with access to an electrical outlet and within the confines of the Pharmacy. Work area can be located away from the busiest areas of the dispensing department; however, Pharmacy must provide easy access to the required documents outlined in the audit notice.
- Pharmacy may not refuse a prescheduled on-site audit at the time of Auditor arrival. Auditor reserves the right to request copies or take digital images (i.e., scanned/photo) of aforementioned documents. A denial of this request will be determined to be denial of access, which is a breach of the audit provisions of the Agreement. The Pharmacy may be subject to immediate suspension or termination for non-compliance.
- Auditors will attempt to minimize any disruption of business processes while on-site.
- Auditor must be given full access to facilities used to support dispensing of Covered Prescription Services billed to WellDyne, including, but not limited to, refrigeration unit used to store Drug Products, compounding area, Drug Product storage area, etc. and Pharmacy staff will accompany Auditor at all times.
- Auditors must be given full access to the books, records, files, lists, signature logs and documentation associated with all transactions related to WellDyne Claims submitted by the Pharmacy. Auditor reserves the right to request copies or take digital images (i.e., scanned/photo) of aforementioned documents. A denial of this request will be determined to be denial of access.
- Auditors must witness the physical extraction of original records and items of facility reviews from the Pharmacy Archives (e.g., Pharmacy records need to be pulled by Pharmacy in view of the auditor). A denial of this request will be determined to be a denial of access.

- Auditor reserves the right to request copies/scanned images of original purchase invoices for Drug Products associated with the submitted Claims. Alternatively, a summary statement of purchases by NDC for the date range requested may be required to be requested of distributors by the Pharmacy and be provided directly to WellDyne by the distributor. Upon request, the Auditor must be provided copies of drug pedigree documentation where applicable and copies of the front and back of all cancelled checks or other proof of payment as deemed acceptable at the WellDyne's sole discretion, to support purchases. Also, upon request, the Auditor must be provided with a comprehensive drug utilization report which includes all payers for NDCs (National Drug Code) requested (PHI redacted). A denial of this request will be determined to be denial of access.
- Auditor reserves the right for an extension of the original desk audit or on-site audit. A denial of this request will be determined to be denial of access.
- Access to Records and Audits. During the term of the Agreement and for a period of five (5) years thereafter, unless specifically restricted to a period less than five (5) years under state law, WellDyne or its designee shall have the right, upon no less than (14) days' notice and at reasonable times, to access, inspect, review, audit (including on-site and desktop audits) and make copies of the Records ("WellDyne Audit"). In addition to the foregoing, Pharmacy shall honor and accommodate all audit requests by Government Authority ("Governmental Audit"). Pharmacy shall pay all costs incurred by Pharmacy in connection with its provision of information for purposes of a Governmental Audit. The audit period shall, however, be ten (10) years in the case of Medicare Part D records.
- Pharmacy must retain an Original Document of Record in its archives as required under State and Federal Law and for a period of no less than five (5) years from the date of the applicable transaction, and ten (10) years in the case of Medicare Part D records.
- Pharmacy must provide a copy of any compound recipe worksheets identifying ingredients used in a Compounded Drug. Provider must submit all ingredients included in each compound and may only submit the NDC associated with the actual ingredients filled/dispensed.
- Each document as listed above is to be filed as an original document in the archives of the Pharmacy, to be retrieved for inspection at the request for audit by Auditor.
- An original or digital image of the signature log will be accepted as audit evidence for receipt of goods.
- Pharmacy will receive written disclosure of initial/preliminary audit findings after the field work for any in-depth audit.
- The Pharmacy (or their pharmacy locations) will be given the opportunity to dispute any audit findings by filing an appeal within thirty (30) days, or as

indicated by state law, from the receipt date of the initial/ preliminary audit results letter. Such documentation must be sent via certified mail or other method that evidences tracking such as FedEx, etc., to the attention of the WellDyne Network Audit Manager, or as otherwise instructed in the initial/ preliminary audit results letter. Upon extenuating circumstances, a request for an extension may be granted at the sole discretion of WellDyne. Receipt of such an extension request must be received in writing within the required thirty (30) days appeal period or as otherwise instructed in the initial/preliminary audit results letter. Failure to submit appeals by the period allowed will subject any applicable discrepancy to recoupment as indicated in the initial/preliminary audit results letter.

- Post-audit documentation must consist of original hard copies of Prescriptions or Authorized Statement (no verbal orders), or other original documentation as approved by WellDyne.
- Final audit findings will be provided after the dispute period has lapsed, in accordance with any applicable state law, and with consideration of any dispute that was filed timely. Audit findings will indicate where a full or partial recoupment is necessary or indicate that a finding is educational only. The Pharmacy will receive a chargeback against future remittances until paid-in-full for any discrepancies found during the audit. Payments to WellDyne are only necessary if the Pharmacy is no longer operating.
- Agreement in effect, or if insufficient payment activity is available to offset the chargebacks within a reasonable period.
- WellDyne at its sole discretion may elect to notify a PSAO of any significant audit findings if the pharmacy in question is affiliated with a PSAO.
- WellDyne shall have the right, with no less than (14) days' notice, at reasonable times, to perform a facility review to inspect the Pharmacy location for compliance. Request for copies or digital images (i.e., scanned/photo) of documents pertaining to the review may be requested. Pharmacy agrees to cooperate with WellDyne during the on-site audit and acknowledges non-cooperation with such on-site audit may result in denial or termination of network participation.
- Facility reviews may include review, as well as documentation of all applicable licensures, proof of identification of employees, compliance with all federal/state regulatory requirements, proof of compliance with return to stock policy, which must be fourteen (14) days or fewer from the date Claims are submitted to WellDyne, various other reviews and inquiries to assure that overall quality assurance measures are implemented.
- Facility reviews may require proof of compliance in providing the Medicare Prescription Drug Coverage and Your Rights notice to all Medicare Members when a Prescription cannot be covered ("filled") under Medicare Part D ("Part D")

benefit in the POS System and the coverage determination results in a 569-reject response.

- Purchases of covered Drug Products for any Claims submitted to WellDyne must be made from a NABP-VAWD (Verified –Accredited Wholesaler Distributors) licensed wholesaler as regulated by state and federal entities. This requirement includes the purchase of non-legend items (e.g., OTC, supplies). Pharmacy must be able to document the source is authorized to include federal/state licensure, oversight by regulatory agencies to include the Food and Drug Administration (FDA), DEA and ability to obtain pedigree information for Drug Products. Pharmacy must promptly comply with any requests to produce such documentation. Any inter- pharmacy transfers must be accurately and completely documented in a manner consistent with federal/state laws, as well as industry standards.
- A Pharmacy may transfer inventory to alleviate a temporary shortage or for the sale, transfer, merger or consolidation of all or part of the business of a pharmacy from or with another pharmacy, whether accomplished as a purchase and sale of stock or business assets.

On the day the Drug Products or medical supplies are transferred, a complete inventory must be taken which documents the drug name, dosage form, strength, NDC, lot number, quantity and date transferred. Additionally, documents must indicate the supplier or manufacturer's name, address, and registration number. All records involved in the transfer must be maintained and accessible for five (5) years.

#### *Desktop and telephone audits*

WellDyne conducts desktop audits and investigational audits to verify the accuracy and validity of Claim submissions. Pharmacies are typically contacted via telephone, fax, or mail and asked to provide photocopies of specific documents and records related to Claims paid to Pharmacy by WellDyne during a specified period. Requested documentation may include, but is not limited to, original Prescriptions, signature logs, computer records, and invoices showing purchase or receipt of dispensed medications. WellDyne will identify any discrepancies found in the documentation and will advise Provider of such via post audit reports.

Provider is required to correct the claims through resubmission if requested by Auditor.

- WellDyne monitors claims data for potential billing errors and reasonable claim submissions daily. If a potential discrepancy is found, an Auditor will contact the Pharmacy, typically via telephone, to inquire about, validate, and help resolve any discrepancy. Unless supporting documentation is required, most of these discrepancies can be validated with minimal correspondence and resolved through Claim reversal and resubmission by Pharmacy.
- Pharmacy is required to answer reasonable telephone inquiries by an Auditor or a designee, as determined solely by WellDyne, to validate a member being

billed, Prescription directions, Compounded Drug ingredients, quantities being dispensed, etc.

- All in-depth desktop audits will be directed by written correspondence.
- Where billing agents are utilized by a Pharmacy, WellDyne may coordinate audits with the billing agent, but Pharmacy remains responsible for all billing outcomes, verification, and validation.
- Network audits may be performed by WellDyne staff, or by an agent authorized solely by WellDyne.
- In cases where the desktop audit is related to a Member complaint, Pharmacy shall respond to desktop audit requests within three (3) business days.

#### *Investigative reviews*

WellDyne conducts investigational reviews to verify the accuracy/validity of Claim submissions, as well as verification of Drug Product and supply purchases. Investigative reviews may be performed as on-site or desktop audits, and encompass all requirements listed in Section B. Pharmacy Audits (Audits) of this manual. Requested documentation may include, but is not limited to, original Prescriptions, signature logs, computer records, distributor year-to-date summaries or invoices of each wholesaler/distributor supporting all Drug Products, including DME purchases and returns. Pharmacy will receive fourteen (14) calendar days, unless another time is dictated by federal/state guidelines or law, to provide the necessary documentation needed to satisfy the review.

WellDyne will identify any discrepancies found in the documentation and will advise Pharmacy of such via a post-review report.

Pharmacy will receive no less than a ten (10) business day appeal timeframe to submit any additional documentation needed to refute the findings.

#### *Please Note:*

All distributor purchase summaries or invoices of each wholesaler/distributor must come directly from the wholesaler/distributor. Summaries or invoices received from the Pharmacy will not be accepted.

#### *Documentation and submission expectations*

Pharmacy shall maintain adequate Prescription, as well as financial records relating to the provision of Covered Prescription Services to our Members, including but not limited to: Pharmacy books/ databases, daily Prescription logs, patient profiles, Prescription hardcopies, Prescriber information, signature/delivery logs, refill information, wholesaler/manufacturer/distributor/all other purchase invoices, business records such as FWA training logs, LEIE/EPLS verifications, availability of notices such as the CMS10147 and other federal/state required documents, policies, including other such documentation necessary for all Covered Prescription Services provided. Pharmacy shall also maintain all policies and procedures related to maintenance of such records.

Pharmacy shall maintain/retain all records described herein for no less than five (5) years from the date of the applicable transaction or as required by law and ten (10) years in the case of Medicare Part D records.

The information provided below is intended to clarify documentation expectations related to items to help Pharmacies avoid problems and be prepared for an audit.

#### *Prescription records*

All Prescription documentation, regardless of the way it has been created, generated, or transmitted shall contain the following: Full name of the Member for whom the Prescription was written and the address of the Member along with a date of birth; Full name and address, telephone number and any other required identifiers of the Prescriber Name, strength, dosage form and quantity of the medication prescribed; Specific dosing directions, if a Prescription contains ambiguous directions the Provider must clarify these directions and note the conversation to clarify; Substitution instructions where applicable, or substitution requested by Member clearly noted; Refill instructions; Miscellaneous or other informational notes as required by applicable laws or regulations; and complete documentation of items, quantities to be dispensed and directions for use for diabetic supplies, as well as insulin.

Prescription records must be updated yearly, or for such a shorter period required by applicable law. If applicable law does not specify a time, WellDyne requires that Prescription hard copies be updated yearly. Update must also include the assignment of a new Prescription number.

WellDyne recommends that Pharmacy document as much information as possible on the Prescription itself, outlining any unusual circumstances that occurred while dispensing the Covered Prescription Service. Such notes may eliminate a question from the Auditor or help resolve a discrepancy.

The hard copy (original and any updates) of the Prescription, including telephone Prescriptions, must contain all data elements required by state pharmacy laws in which Pharmacy is located and all Prescriber instructions — including Product Selection Code instructions — that support the Pharmacy Claim transmission.

Prescriptions in which the dosage/quantity is changed require either written documentation on the Prescription or a new hard copy Prescription to be issued. When the Prescriber writes "as directed", documentation as to the exact directions or, at a minimum, the maximum (up to) dose of medication taken per day must be documented on the hard copy or electronically and be viewable upon request. Only Prescriptions generated by the Prescriber are accepted as post audit documentation for "as directed" Prescriptions at the WellDyne's sole discretion.

If less or more medication (if permitted) is given than ordered by the Prescriber, the reason for this must be documented. Any increase in the amount of Drug Product over the original prescribing order must be documented for Prescriber authorization.

#### *Wholesaler, manufacturer, and distributor invoices*

Wholesaler, manufacturer, and distributor invoices and other purchase invoices and documents must be accessible, maintained for a minimum of five (5) years or as required by law or regulation and ten (10) years in the case of Medicare Part D records to substantiate that the Drug Products dispensed were purchased from an authorized source regulated by the federal/state entities and NABP-VAWD (Verified –Accredited Wholesaler Distributors), to include valid licensure in the state the Drug Product is dispensed. Purchases for any Clean Claims submitted to WellDyne must be made from a licensed wholesaler as regulated by federal/state entities. This requirement includes the purchase of non-legend items (e.g., over-the-counter supplies). Pharmacy must be able to document the source is authorized to include state or federal licensure, oversight by regulatory agencies to include the Food and Drug Administration (FDA) and DEA and ability to obtain pedigree information for Drug Products. Pharmacy must promptly comply with any requests to produce such documentation. If Pharmacy fails to promptly provide such requested documents or the wholesaler is not NABP, VAWD (Verified – Accredited Wholesaler Distributors), WellDyne may immediately offset 100% of the amount for any of the paid claims in question and impose additional fines or penalties. Pharmacy shall remain responsible for the validation a wholesaler, from which they are provided Drug Products, has valid pedigree. Pharmacy shall maintain adequate records to further validate purchases from wholesalers to include canceled check information available for Audit. Adequate records are proof of purchases which indicate price, drug name, dosage form, strength, NDC, lot number and quantity.

Pharmacy may not enter a captive pharmacy arrangement, whereby the pharmacy enters into agreement for the marketing and dispensing of Drug Products specifically for a manufacturer without disclosure to WellDyne, as well as written permission by WellDyne.

#### *Signature log — hard copy or electronic*

Pharmacy shall require the signature of the Member or the Member 's appointed/authorized representative on a permanent record before dispensing any Prescription. All logs must be maintained for all Claims submitted on-line via the POS System to WellDyne.

At each Pharmacy location, Pharmacy shall maintain a hard copy or, if pre-approved by WellDyne, an electronic or manual signature log which contains the following: the Prescription number; the date the Drug Product is received by the Member; and the signature of each Member who receives a Drug Product or the signature of his/her designee, and the authorization to release information to a third-party program.

Pharmacy must obtain a legible written signature or electronic capture that corresponds to a matched printed name or another authorized person to confirm receipt of the Prescription product. Capture of non-signature data elements to document receipt of the Covered Prescription Service (e.g., electronic delivery notice or point-of-sale information) must be only upon express permission of WellDyne. Proper verification of the person picking up the Covered Prescription Service is essential to ensure the

deterrence of potential fraud and abuse. If delivered to a home or business address, Pharmacy must obtain the signature of the Member or his/her designee at the time of delivery. If patient is sent monthly billing statements, Pharmacy may insert a form listing the dates of fill and Prescription numbers; the eligible Member or Member's appointed/authorized representative should be instructed to sign and return the form with his/her payment. Providers using mail services must include information to document tracking of shipment, confirmation of delivery, or other proof of delivery. These Prescription signature logs must be in date order where appropriate and readily accessible.

### *LTC providers*

WellDyne reserves the right to audit an LTC Pharmacy 's books, records, Prescription files, and signature logs for the purpose of verifying Claims submission information. LTC Pharmacies are required to have a signed Prescriber 's order available for audit. These orders may be in the form of a standard prescription or copies of signed Prescriber 's orders from a medical chart. Record retention is important, and time to retrieve these documents is considered in complying with audit requirements. LTC Pharmacies are not required to have a signature from the member as proof of receipt. However, LTC Pharmacies must have delivery logs, manifests or other WellDyne approved proof of delivery of Covered Prescription Services to facilities readily available during an audit.

Abuse of the Short Cycle Dispensing regulations as defined by CMS and implemented on 1/1/2013, will be subject to audit and recovery of overpayments resulting from abuse and any attempt to achieve multiple dispensing fees based on days' supply manipulation. WellDyne may also audit to find attempts to gain more than two (2) dispensing fees in a one (1) month period.

LTC Network Providers must dispense drugs and report information as required by 42 CFR §423.154. WellDyne shall reimburse LTC Pharmacies in accordance with 42 CFR §423.154.

### *Post-audit reporting*

Pharmacy may receive a post-audit report if specific Claims require additional documentation. Additional documentation is typically required within a thirty (30) calendar-day period to contest any findings identified unless another time is dictated by federal/state guidelines or Law. At the completion of the audit, Pharmacy may also receive a final audit report with the Claims identified as discrepant and due for recovery. All documentation must be received no later than thirty (30) calendar days from the date of the discrepancy report. Beyond that date, the audit will be considered final.

### *Miscellaneous audit information*

In situations where cumulative errors rise to the level of negligence or FWA, as determined solely by WellDyne, WellDyne reserves the right to extrapolate audit sample exceptions against the entire population under audit, subject to applicable law or Government Authority.

The following is a partial list of audit violations which could be perpetrated by a Pharmacy resulting in Claims being recovered in total and no reimbursement will be

forthcoming for actual dispensed quantity. In addition, legal or other action may be taken against the Pharmacy, including immediate termination of the Agreement:

- Billing for a Brand Name Drugs and dispensing Generic Drugs
- Billing of an NDC for other than what was dispensed
- Overbilling of quantity prescribed
- Inappropriate billing of Compound Drugs
- Claims for Covered Prescription Services that include as a component of the Compound Drug and NDC for a repackaged drug; or
- Drugs imported or reimported into the United States, including bulk powders utilized in Compound Drugs where part of the final Compound Drug dispensed is composed of an imported component are subject to full recovery
- Undocumented substitution
- Non-covered item billed as covered
- Duplicate Claim billed
- Billing for more Drug Products than dispensed (pill shorting)
- Submitting Claims for Drug Products not rendered and/or prescribed
- Submission of dummy DEA/NPI or Invalid DEA/NPI numbers to obtain a paid response
- Billing Claims for more fills or refills than were authorized or illegal refill of a schedule II narcotic Prescription
- Covered Prescription Services filled after their legal time limit
- Billing for invalid Prescriptions due to lack of a legal Prescriber, forgery, or false or fictitious documents
- Covered Prescription Services filled incorrectly based on original order
- Refills too soon that were paid due to a prior days' supply violation
- Inability to locate the original Prescription (missing)
- Covered Prescription Services lacking sufficient proof of delivery to Member
- Covered Prescription Services where a member denies receiving Drug Products billed
- Covered Prescription Services where Prescriber denies prescribing Drug Products billed
- Covered Prescription Services returned to stock but not reversed

- Prescriptions missing date written, or filled before date authorized
- Prescriptions missing Prescriber signature
- Prescription missing any other required information by federal/state government or is otherwise not a legal Prescription
- LTC Pharmacy billing for unused Drug Products and not applying credit to Member
- Drug Product to be billed under Medicare Part A or Part B versus under Part D
- Inappropriate, inaccurate, or incomplete record-keeping practices related to billed Prescriptions
- As Directed/UD SIGS: Pharmacy must submit an accurate day's supply based on Prescriber's directions for use. In cases where directions are not specific, such as "Use as Directed," "UD," etc., Pharmacy must obtain clarification from the Prescriber as to the specific directions on which to base the correct days' supply submitted for the quantity billed. Specific directions must be noted on the Prescription hard copy or in Pharmacy's electronic records system
- Use of coupons when prohibited by Benefit Plan including, but is not necessarily limited to, programs funded by the federal government (e.g., Medicare, Retiree Drug Subsidy (RDS) plans and Medicare Part D)
- The following is a partial list of audit violations which could be perpetrated by a Pharmacy where Claims will be recovered for a partial reclaim of the Covered Prescription Services or recovered in total if a pattern of Abuse is evident. In addition, legal or other action may be taken against the Pharmacy, including termination of the Agreement:
  - Overbilling of quantity in relation to days' supply that exceeds plan maximums, or not in conformance with that prescribed.
  - Billing for larger pack sizes when one smaller pack size will meet the directions of the Prescriber and remain within the Benefit Plan's maximum days' supply
  - Prescription splitting to obtain multiple dispensing fees or undermine prior authorization or quantity limits, etc.
  - Billing multiple lower strengths when one higher strength Drug Product is prescribed.
  - Billing for a brand name Drug with DAW 1 when a Prescriber has not specified "Do Not Substitute" on the prescription, or other inappropriate use of DAW codes.

WellDyne reserves the right to assess a penalty equal to the entire amount of the Claim (including copayment) for each violation, in addition to the Covered Prescription Services value or difference in billing being recovered.

Material repetition or pattern of practice of any given category of audit violation or the material combination of various categories of violations discovered during an audit may subject Pharmacy to further disciplinary action potentially including termination from WellDyne Network(s).

Instances of alleged FWA discovered during audit shall subject Pharmacy to immediate termination.

Withheld amounts due to audit findings that are not documented within three (3) months are subject to refunding to Clients without further appeal.

Subject to applicable Law, WellDyne at its sole discretion may suspend Claims payments to Pharmacy for an indefinite period on behalf of any or all Benefit Plan Sponsors, including but not limited to when at the request of any Government Authority, direction by subpoena, non-response to an audit request, pending the outcome of an Audit and/or reasonable belief Pharmacy is engaged in fraudulent or illegal activity.

#### *Audit dispute resolution procedure and audit collections/final audit remedies*

WellDyne maintains an ongoing Pharmacy Audit Program to ensure Pharmacies are complying with their Agreement. Notwithstanding rights included in the Agreement or the Pharmacy Manual, WellDyne has established the Pharmacy Network Evaluation Committee (PENAC); an internal hearing process that is independent of the individual Auditor who conducted the audit, allowing an audited Pharmacy to submit a request for reconsideration of an unfavorable final audit determination.

Please refer to the audit communications as provided by Auditors for discrepancies identified and the actions a Pharmacy may take to remedy such discrepancies. Pharmacy shall exhaust all appeal options prior to being able to qualify for a PENAC review. Please be aware the PENAC process is not a vehicle for submission of new materials for inclusion in the audit review but is designed to provide a re-determination of previously submitted post-audit documentation. The PENAC process is not available to Pharmacy terminated, disciplined or otherwise the subject of an investigation for reasons associated with suspected fraud or abuse including prescriber denials, member denials, or inventory shortages.

Requests for reconsideration are submitted to, and reviewed by, the PENAC, which is comprised of pharmacists and other professionals from within WellDyne, but otherwise not associated with the WellDyne's Auditor or Network Audit Department team responsible for the audit being reviewed.

In cases where Pharmacy disagrees with the WellDyne's decisions or policies relating to final audit findings they are given a one-time opportunity to respond to final audit findings by filing a written request for reconsideration within thirty (30) days from the date of the

final audit report. Documentation related to the request for reconsideration must be received by WellDyne within thirty (30) days of the Final Findings Letter.

WellDyne may begin offset of audit finding amounts against any future payments due to Pharmacy and impose certain fines or penalties prior to the outcome of the PENAC process. WellDyne has the right to assess reasonable fines, penalties, and fees to cover unexpected costs. These actions may include the imposition of fines or penalties due to repeated audits, probation, termination from the network and corrective action plans.

#### *Prohibited activities by Pharmacy and associated penalties*

Pharmacy is subject to penalties or sanctions in the event it is determined by WellDyne during communications between Pharmacy and an existing Client or a potential Client:

(i) Pharmacy disclosed confidential information to a client or a potential Client or (ii) disrupted a WellDyne relationship with its existing Client or with a potential client.

Penalties shall be invoked in amounts at a minimum of \$5,000 per incident/per day, may be subject to additional actions taken by WellDyne, including, as well as up to termination from participation, withdrawal, and/or the holding of funds as deemed necessary by WellDyne.

#### *Non-solicitation*

Any violation of this non-solicitation section shall be deemed a material breach, and WellDyne shall have the right to terminate the Agreement with respect to Pharmacy or any of its individual locations or impose penalties as WellDyne deems appropriate to address such violations, in addition to any other rights WellDyne has in the Agreement, at law or in equity.

Pharmacy will refrain from advising or soliciting any Members with plans utilizing WellDyne for any reason, including, but not limited to improving compensation.

Pharmacy will refrain from advising, counseling, or soliciting any plans to terminate its relationship with WellDyne for any reason, including, but not limited to improving compensation level or the termination of the Agreement. Pharmacy shall not engage in any conduct or communication intended to discredit, defame, or disparage WellDyne or Client and/or the quality of WellDyne's or Client's services or products. Pharmacy acknowledges and agrees that any potential violation of this section by Pharmacy would cause WellDyne immediate and irreparable harm or loss that cannot be fully remedied by monetary damages. Accordingly, in the event of any violation of this section by Pharmacy, WellDyne shall be entitled to all legal and equitable relief, including, but not limited to the issuance of a temporary restraining order and/or immediate termination of the Agreement.

Pharmacy may not obtain its patients via cold-calling or unsolicited methods of obtaining a member's billing information or to make offers of contacting the Member's Prescriber. All submission of Claims for a fill or refill of a Drug Product by Pharmacy must be initiated in accordance with a Member's knowledge and authorization.

Pharmacy shall not solicit, as a matter of routine business practice, a Member for mail delivery or deliver any Covered Prescription Services to a Member by mail (e.g., UPS, USPS, Fed-Ex) except upon the advance written approval of WellDyne, which approval may be refused in WellDyne's sole discretion.

### Non-compliance

Pharmacy must provide Covered Prescription Services related to a covered item to all Members of all Benefit Plan Sponsors in compliance with the PM and as set forth within the Agreement. Non-compliance may include, but is not limited to, the disclosure of confidential information or data, submitting an incorrect DAW code, submitting an inaccurate U&C price, submitting incorrect Claim submission data, submitting an incorrect NDC number, the collection of a patient pay amount that differs from the amount specified in the Claims response, failure to dispense an emergency supply of a covered item to a Member as required by law, failure to dispense covered Drug Product based on reimbursement received and the refusal to accept an identification card for a Member.

Should the Pharmacy be deemed non-compliant, certain remediation actions may apply, including but not limited to corrective action, probation, termination of the Agreement, and any other available recourse.

Should the Pharmacy's actions or inactions result in any fees, interest penalties, damages, withholds, judgments, financial obligations or other charges imposed upon WellDyne, such shall be paid in full by Pharmacy within the period specified by WellDyne.

For each network requirement for which the Pharmacy is deemed noncompliant, WellDyne, in its sole discretion may assess against Pharmacy up to a \$100 administration fee per occurrence.

WellDyne reserves the right to offset any amounts owed to Pharmacy and any such amounts owing to WellDyne for discrepant Claims or other charges for non-compliance or audit-related costs.

### Termination and appeal process

Except for non-renewal of the Agreement at the end of a term thereof, Pharmacies terminated in accordance with the Agreement or PM will be provided a written notice describing the reason(s) for such termination and an opportunity to request a hearing to appeal such termination.

Pharmacies terminated from participation may apply for reinstatement five (5) years from the date of such termination. Such reinstatement is at WellDyne's sole discretion.

Termination of Pharmacies participation in the Agreement for any reason pursuant shall not affect the rights and obligations of the parties arising out of any transactions occurring prior to the effective date of such termination.

After the effective date of Pharmacies termination of participation in the Agreement in its entirety, Pharmacy shall make an accounting of all monies due hereunder to WellDyne or any Client and shall pay such amount due to WellDyne, including payment for any non-Clean Claims or outstanding balances from reversed, but not reprocessed Claims. Pharmacy acknowledges the right of WellDyne or WellDyne's Clients to inform Client's Members of Pharmacy's termination, suspension, limitation, exclusion, or revocation and agrees to cooperate with WellDyne and/or WellDyne's Clients with transferring any Prescriptions to a Pharmacy.

### Delegation

Pharmacy shall not delegate any service, activity or other obligation required of it under the Agreement, as amended, (including the provision of Covered Prescription Services by Network Pharmacy Provides to Plan Members), to an Affiliate or third party, without the prior written consent of WellDyne (which consent shall not be deemed to create any liability for WellDyne whatsoever unless otherwise required by applicable law), and when necessary, all applicable Clients, as determined in the sole and absolute discretion of each of them, as may be communicated by WellDyne. No consent may be obtained until WellDyne has received a fully executed copy of each agreement between Pharmacy and a delegate that relates to the proposed delegation. Any such agreement must provide that it will terminate (i) completely if WellDyne revokes an agreement on the delegation or (ii) as to an affected Client if the Client revokes the delegation. Any such delegation, if consented to (and "Approved Delegation"), shall be performed by the delegate in accordance with the Clients' respective contractual obligations and in accordance with Pharmacy's contractual obligations hereunder. Pharmacy agrees that any agreements of Pharmacy with respect to an Approved Delegation shall be in writing, signed by the parties to be bound thereby and in compliance with all applicable laws and regulations. In the event that a delegate of Pharmacy fails or is unable (for any reason whatsoever) to perform in a satisfactory manner any services, activities, or other obligations which have been sub-delegated pursuant to an Approved Delegation, then WellDyne or any affected Client shall have the right to suspend, revoke or terminate such Approved Delegation effective upon the date set forth in a written notice furnished to Pharmacy and Pharmacy shall continue to be responsible to perform such duties and obligations of the Agreement. Additionally, an affected Client shall have the right to institute corrective action plans or seek other remedies or curative measures respecting the unsatisfactory Approved Delegation consistent with applicable laws and regulations. Any attempted sub-delegation by Pharmacy is not an Approved Delegation shall be invalid and of no force or effect.

## Appendix A APPENDIX

### Guidance for Pharmacies - Insulin, Inhalers and Ophthalmic products

#### *Insulin and diabetic supplies*

When submitting a claim, pharmacies shall only submit the NDC associated with the actual insulin or diabetic supply product in which the prescription is written. Diabetic insulin and supplies must be calculated to accurately submit the days' supply. Directions that indicate as needed or as directed require intervention documentation with the prescriber on the original prescription.

If Prescriber indicates as directed as per sliding scale, pharmacies shall obtain the dosage range, document the range on the original prescription and calculate the days' supply by using the maximum (up to) daily dosage.

#### *Inhalers and inhalation products*

When submitting claims for inhalers pharmacies are required to enter the appropriate decimal quantity as prescribed and according to the medication guidelines and participant's benefit plan. For some medical conditions it may be necessary to dispense more than one inhaler if prescribed and allowed by benefit plan.

#### *Ophthalmic Drops*

Eye drops should be calculated using 15 drops per mL, unless otherwise specified by the manufacturer. Prescriptions with defined length of therapy may use the specified length of therapy as the days' supply for the claim when the smallest package size is being dispensed (e.g., 5ml ophthalmic with acute therapy of 5 days).

| <b>Days' Supply Total Quantity Dispensed in MLs</b> |                      |                    |                     |                     |                     |
|---|----------------------|--------------------|---------------------|---------------------|---------------------|
| <b>Drops/day</b>                                    | <b>2.5 ML Bottle</b> | <b>5 ML Bottle</b> | <b>10 ML Bottle</b> | <b>15 ML Bottle</b> | <b>20 ML Bottle</b> |
| <b>1</b>  | 37                   | 75                 | N/A                 | N/A                 | N/A                 |
| <b>2</b>  | 18                   | 37                 | 75                  | N/A                 | N/A                 |
| <b>3</b>  | 12                   | 25                 | 50                  | 75                  | N/A                 |
| <b>4</b>  | 9                    | 18                 | 37                  | 56                  | 75                  |
| <b>6</b>  | 6                    | 12                 | 25                  | 37                  | 50                  |
| <b>8</b>  | 4                    | 9                  | 18                  | 28                  | 37                  |

\* If the minimum quantity as represented by the manufacturer smallest available unit-of-use causes a rejection, with notation of a maximum day's supply, it is allowable to resubmit with the communicated days' supply which represents the plan maximum.

- Pharmacy shall, if available and in accordance with 42 CFR § 423.132, when dispensing a covered Medicare Part D Drug Product, inform the participant at the POS of the lowest-priced, generic equivalent version of that covered Medicare Part D Drug Product.

Any subsequent changes in the original dispensing limitations (e.g., increase in quantity) or refill authorizations approved by the prescriber must be documented on the original hard copy prescription or in a readily retrievable electronic format acceptable by the State Board of Pharmacy in which pharmacy is located.

## Appendix B Regulatory Programs

This Appendix includes regulatory program requirements in respect of Medicare Part D for participating pharmacies, Indian Health Service providers and long-term care pharmacies.

1. Definitions. For purposes of this Appendix:
  - a. "Agreement" means the participating pharmacy agreement between the pharmacy and WellDyne.
  - b. "Federal health care program" shall be as defined in section 1128B(f) of the Social Security Act.
  - c. "HIPAA" means the Health Insurance Portability and Accountability Act of 1996 and regulations implementing the act, as amended from time to time, including by the Health Information Technology for Economic and Clinical Health (HITECH) Act.
  - d. "Ineligible Person" means an individual or entity (1) excluded from participation or otherwise declared ineligible to participate in Federal health care programs, as identified on the List of Excluded Individuals/Entities maintained by the Office of Inspector General, U.S. Department of Health and Human Services, (2) debarred from participation or otherwise declared ineligible to participate in Federal procurement or nonprocurement programs, as identified on the Excluded Parties List System maintained by the General Services Administration, or (3) convicted of a criminal offense related to the provision of health care items or services covered by a Federal health care program or Federal procurement or nonprocurement program, but not yet excluded, debarred or otherwise declared ineligible to participate in such programs.
  - e. "Pharmacy Manual" means this manual.
2. Regulatory Program Exhibits
  - a. Regulatory Exhibit 1 – Part D Addendum
  - b. Regulatory Exhibit 2A – I/T/U Pharmacy Part D Addendum
  - c. Regulatory Exhibit 2B – Indian Health Addendum to Medicare Part D Plan Agreement
  - d. Regulatory Exhibit 3 – LTC Pharmacy Part D Addendum
3. Pharmacy Manual - Participating Pharmacy shall comply with the Pharmacy Manual. The Pharmacy Manual supplements and is part of and incorporated into the Agreement. The Pharmacy Manual shall include requirements for Participating Pharmacy to participate in WellDyne's pharmacy benefit management, complaint, and other programs, including government program requirements. WellDyne shall maintain the Pharmacy Manual and update the manual from time to time. WellDyne shall publish the most current version of the Pharmacy Manual on its website. Pharmacy shall be responsible for ensuring compliance with the most recent version of the Pharmacy Manual.
4. Compliance. The Agreement is subject to applicable laws, rules and regulations, and accreditation standards, including during the term of the Agreement new or changes to (1) applicable laws, rules, or regulations, (2) decisions of a Court or guidance of an administrative body interpreting any of the foregoing, or (3) accreditation standards that apply to WellDyne or its plan sponsor clients.
  - a. In carrying out its responsibilities under the Agreement, each party shall comply with all applicable laws, rules, and regulations, including (1) Federal laws, rules and regulations designed to prevent or ameliorate fraud, waste, and abuse, including, but not limited to, applicable provisions of Federal criminal law, the

False Claims Act (31 U.S.C. 3729 et. seq.), and the anti-kickback statute (section 1128B(b)) of the Social Security Act); and (2) HIPAA administrative simplification rules at 45 CFR parts 160, 162, and 164.

- b. WellDyne may require, and Participating Pharmacy shall provide, access to Member records for purposes of managing pharmacy benefits under a Plan and any other lawful purpose.
- c. Ineligible Persons. Participating Pharmacy shall ensure that no individual or entity carrying out Participating Pharmacy's responsibilities under the Agreement is an Ineligible Person.
- d. Compliance Programs. Participating Pharmacy shall participate in programs instituted by WellDyne for prevention of fraud, waste, and abuse, as described in the Pharmacy Manual.

## Regulatory Exhibit 1 – Part D Addendum

1. Additional Definitions.
  - a. “CMS” means Centers for Medicare and Medicaid Services within HHS.
  - b. “CMS Contract” means the contract between CMS and the Medicare Plan Sponsor.
  - c. The term “date of completion of an audit” means the completion of audit by HHS, the Government Accountability Office, or their designees, or a Medicare Plan Sponsor, or Medicare Plan Sponsor contractor or related entity.
  - d. “Downstream Entity” for purposes of this Exhibit means a contractor of Participating Pharmacy providing products or services covered under a Medicare Part D or MA-PD Plan to Medicare Members.
  - e. The term “final date of the contract period” means the final term of the CMS Contract.
  - f. “HHS” means U.S. Department of Health and Human Services.
  - g. “MA-PD plan” means a Medicare Part C plan with Part D benefits.
  - h. “Medicare Plan” means a Medicare Part D plan or MA-PD plan.
  - i. “Medicare Plan Sponsor” means WellDyne or a plan sponsor of a Medicare Plan contracted with WellDyne to manage pharmacy benefits.
  - j. “Part D plan” means a prescription drug plan under Medicare Part D.
  - k. “Member” means a member enrolled in a Medicare Plan.
2. Participating Pharmacy agrees and shall require Downstream Entities to agree that:
  - a. HHS, the Comptroller General, or their designees have the right to audit, evaluate, collect, and inspect any books, contracts, computer, or other electronic systems, including medical records and documentation of Participating Pharmacy, Downstream Entity and related entities related to the CMS Contract.
  - b. HHS, the Comptroller General or their designees have the right to audit, evaluate, collect, and inspect any records under this section directly from Participating Pharmacy or Downstream Entity.
  - c. For records subject to review under the foregoing paragraph of this section, except in exceptional circumstances, CMS will provide notification to the Medicare Plan Sponsor that a direct request for information has been initiated.
3. Participating Pharmacy and Downstream Entity shall not hold a Member liable for fees that are the obligation of the Medicare Plan Sponsor. [42 CFR 422.504(i)(3)(i) and 422.504(g)(1)(i); 42 CFR 423.505(i)(3)(i) and 422.505(g)(1)(i)]
4. For MA-PD Plans with Members eligible for both Medicare and Medicaid, such Members will not be held liable for Medicare Part A and B cost sharing when the state is responsible for paying such amounts. Participating Pharmacy shall be informed of Medicare and Medicaid benefits, and rules for Members eligible for Medicare and Medicaid. Medicare Plan Sponsors of MA-PD Plans may not impose cost-sharing that exceeds the amount of cost-sharing that would be permitted with respect to the individual under title XIX (Medicaid) if the individual were not enrolled in such a plan. Participating Pharmacy will (a) accept the WellDyne payment under this Agreement as payment in full, or (b) bill the appropriate state source. [42 CFR 422.504(g)(3)(iii)]
5. Participating Pharmacy agrees and shall require Downstream Entities to agree that any services or other activity performed by Participating Pharmacy or Downstream Entity in accordance with this Agreement are consistent and comply with the Medicare Plan Sponsor’s contractual obligations to CMS. [42 CFR 422.504(i)(3)(iii); 42 CFR 423.505(i)(3)(iii)]
6. Participating Pharmacy agrees and shall require Downstream Entities to agree that Participating Pharmacy and Downstream Entity must comply with all applicable Federal laws, regulations, and CMS instructions. [42 CFR 422.504(i)(3)(iv); 42 CFR

423.505(i)(3)(iv)]

7. Payment Provisions.
  - a. For MA-PD Plans, Medicare Plan Sponsor shall reimburse Participating Pharmacy for clean claims in accordance with the payment provisions in the reimbursement section of the Agreement. [42 CFR 422.504(c) and 42 CFR 422.520(b)(1) and (2)]
  - b. For Part D Plans, Medicare Plan Sponsor shall issue, mail, or otherwise transmit payment with respect to all clean claims, as defined below, submitted by network pharmacies (other than mail-order and long-term care pharmacies) within:
    - i. 14 days after the date on which the claim is received, for an electronic claim:  
or
    - ii. 30 days after the date on which the claim is received, for any other claim.  
As used in paragraph (b), a “clean claim” means a claim that has no defect or impropriety (including any lack of any required substantiating documentation) or circumstance requiring special treatment that prevents timely payment of the claim from being made under this section. A claim is considered to have been received (1) on the date on which the claim is transferred, for an electronic claim, or (2) the 5th day after the postmark day of the claim or the date specified in the time stamp of the transmission, for any other claim, whichever is sooner. [42 CFR 423.505(i)(3)(v); 423.520(a) and (b)]
8. Participating Pharmacy agrees and shall require Downstream Entities to agree to comply with the confidentiality and Member record accuracy requirements, including (1) abiding by all Federal and state laws regarding confidentiality and disclosure of medical records, or other health and enrollment information, (2) ensuring that medical information is released only in accordance with applicable Federal or state law, or pursuant to court orders or subpoenas, (3) maintaining the records and information in an accurate and timely manner, and (4) ensuring timely access by enrollees to the records and information that pertain to them. [42 CFR 422.504(a)(13) and 42 CFR 422.118; 42 CFR 423.505(b)(14); and 42 CFR 423.136]
9. With respect to MA-PD Plans, Participating Pharmacy acknowledges that the Medicare Plan Sponsor oversees and is accountable to CMS or any functions and responsibilities described in Medicare Advantage regulations. [CMS Medicare Managed Care Manual, Ch. 11, s. 100.4]
10. None of Medicare Plan Sponsor’s activities or responsibilities under its CMS Contract are delegated to Participating Pharmacy in this Agreement. However, if Medicare Plan Sponsor delegates its activities or responsibilities under its CMS Contract, the following requirements shall apply:
  - a. Every contract must specify delegated activities and reporting responsibilities.
  - b. Each contract must either provide for revocation of the delegation activities and reporting responsibilities described in the foregoing paragraph or specify other remedies in instances when CMS or Medicare Plan Sponsor determine that the parties have not performed satisfactorily.
  - c. Every contract must specify that Medicare Plan Sponsor on an ongoing basis monitors the performance of the parties.
  - d. Each contract must specify that the related entity, contractor, or subcontractor must comply with all applicable Federal laws, regulations, and CMS instructions. [42 CFR 422.504(i)(4); 42 CFR 423.505(i)(4)]
11. Pricing Source. WellDyne shall, and shall require other Medicare Plan Sponsors to:
  - a. Update any prescription drug pricing standard based on the cost of the drug used for reimbursement of network pharmacies by Medicare Plan Sponsor on January 1 of each contract year and not less frequently than once every 7 days thereafter.
  - b. Indicate the source used for making any such updates; and

- c. Disclose all individual drug prices to be updated to the applicable pharmacies in advance of their use for reimbursement of claims, if the source for any prescription drug pricing standard is not publicly available. [42 CFR 423.505(b)(21) and 505(i)(3)(vii)]  
The term “prescription drug pricing standard” means any methodology or formula for varying the pricing of a drug or drugs during the term of a pharmacy reimbursement contract that is based on the cost of a drug, which includes, but is not limited to, drug pricing references and amounts based on any of the following:
  - (1) Average wholesale price.
  - (2) Wholesale acquisition cost.
  - (3) Average manufacturer price.
  - (4) Average sales price.
  - (5) Maximum allowable cost.
  - (6) Other cost, whether publicly available or not. [42 CFR 423.501]
- 12. Participating Pharmacy shall submit claims to Medicare Plan Sponsor or its intermediary whenever the membership ID card is presented or on file at the pharmacy unless the Member expressly requests that a particular claim not be submitted to Medicare Plan Sponsor or its intermediary. [42 CFR 423.120(c)(3)]
- 13. Participating Pharmacy shall submit claims via a real-time claims adjudication system. (Note: The foregoing does not apply to Participating Pharmacies operated by Indian Health Service, or Indian tribe, tribal organization, or urban Indian organization pursuant to the Indian Health Care Improvement Act.) [42 CFR 505(j) and (b)(17)]
- 14. The parties acknowledge and shall comply with the following: Medicare Plan Sponsor is required to provide Members with access to negotiated prices for Medicare Plan covered drugs included in the plan’s formulary. Negotiated prices must be provided even if no benefits are payable to the beneficiary for Medicare Plan covered drugs because of the application of any deductible or 100 percent coinsurance requirement following satisfaction of any initial coverage limit. Negotiated prices must be provided when the negotiated price for a Medicare Plan covered drug under Medicare Plan Sponsor’s benefit package is less than the applicable cost-sharing before the application of any deductible, before any initial coverage limit, before the annual out-of-pocket threshold, and after the annual out-of-pocket threshold. [42 CFR 423.104(g)]  
Negotiated prices means prices for Medicare Plan covered drugs that meet all the following:
  - (1) Medicare Plan Sponsor (or other intermediary contracting organization) and the network dispensing pharmacy or other network dispensing provider have negotiated as the amount such network entity will receive, in total, for a particular drug.
  - (2) Are inclusive of all price concessions from network pharmacies except those contingent price concessions that cannot be determined at the point-of-sale; and
  - (3) Include any dispensing fees; but
  - (4) Excludes additional contingent amounts, such as incentive fees, if these amounts increase prices and cannot be determined at the point-of-sale.
  - (5) Must not be rebated back to the Medicare Plan Sponsor (or other intermediary contracting organization) in full or in part. [42 CFR 423.100]
- 15. Medicare Plan Sponsor and Participating Pharmacy acknowledge and shall comply with CMS requirements regarding charging/applying the correct cost sharing amount. [42 CFR 423.104]
- 16. Except where waived by CMS in accordance with 42 CFR 432.132(c), Participating Pharmacy shall, when dispensing a Medicare Plan covered drug, inform the Member of any differential between the price of that drug and the price of the lowest priced generic version of that Medicare Plan covered drug that is therapeutically equivalent and

bioequivalent and available at that pharmacy, unless the particular Medicare Plan covered drug being purchased is the lowest-priced therapeutically equivalent and bioequivalent version of that drug available at that pharmacy. [42 CFR 432.132]

17. WellDyne may include additional requirements related to Medicare program participation in the Pharmacy Manual.

## Regulatory Exhibit 2A - I/T/U Pharmacy Part D

Provisions of this Exhibit apply to Participating Pharmacies that are pharmacies or dispensaries operated by the Indian Health Service, or an Indian tribe, tribal organization or urban Indian organization participating in Medicare Plans and control over any conflicting provisions in the Agreement.

1. Additional Definitions.
  - a. "CMS" means Centers for Medicare and Medicaid Services within HHS.
  - b. "CMS Contract" means the contract between CMS and the Medicare Plan Sponsor.
  - c. The term "date of completion of an audit" means the completion of audit by HHS, the Government Accountability Office, or their designees, or a Medicare Plan Sponsor, or Medicare Plan Sponsor contractor or related entity.
  - d. "Downstream Entity" for purposes of this Exhibit means a contractor of Participating Pharmacy providing products or services covered under a Medicare Part D or MA-PD Plan to Medicare Members.
  - e. The term "final date of the contract period" means the final term of the CMS Contract.
  - f. "HHS" means U.S. Department of Health and Human Services.
  - g. "MA-PD plan" means a Medicare Part C plan with Part D benefits.
  - h. "Medicare Plan" means a Part D plan or MA-PD plan.
  - i. "Medicare Plan Sponsor" means WellDyne or a plan sponsor of a Medicare Plan contracted with WellDyne to manage pharmacy benefits.
  - j. "Part D plan" means a prescription drug plan under Medicare Part D.
  - k. "Member" means a member enrolled in a Medicare Plan.
2. Participating Pharmacy agrees and shall require Downstream Entities to agree that:
  - a. HHS, the Comptroller General, or their designees have the right to audit, evaluate, collect, and inspect any books, contracts, computer, or other electronic systems, including medical records and documentation of Participating Pharmacy, Downstream Entity and related entities related to the CMS Contract.
  - b. HHS, the Comptroller General or their designees have the right to audit, evaluate, collect, and inspect any records under this section directly from Participating Pharmacy or Downstream Entity.
  - c. For records subject to review under the foregoing paragraph of this section, except in exceptional circumstances, CMS will provide notification to the Medicare Plan Sponsor that a direct request for information has been initiated.
  - d. HHS, the Comptroller General's, or their designee's right to inspect, evaluate, and audit any pertinent information for any particular contract period exists through 10 years from the final date of the contract period or from the date of completion of an audit, whichever is later. [42 CFR 422.504(i)(2); 42 CFR 423.505(i)(2)]
3. Participating Pharmacy and Downstream Entity shall not hold a Member liable for fees that are the obligation of the Medicare Plan Sponsor. [42 CFR 422.504(i)(3)(i) and 422.504(g)(1)(i); 42 CFR 423.505(i)(3)(i) and 422.505(g)(1)(i)]
4. For MA-PD Plans with Members eligible for both Medicare and Medicaid, such Members will not be held liable for Medicare Part A and B cost sharing when the state is responsible for paying such amounts. Participating Pharmacy shall be informed of Medicare and Medicaid benefits, and rules for Members eligible for Medicare and Medicaid. Medicare Plan Sponsors of MA-PD Plans may not impose cost-sharing that exceeds the amount of cost-sharing that would be permitted with respect to the

individual under title XIX (Medicaid) if the individual were not enrolled in such a plan. Participating Pharmacy will (a) accept the WellDyne payment under this Agreement as payment in full, or (b) bill the appropriate state source. [42 CFR 422.504(g)(3)(iii)]

5. Participating Pharmacy agrees and shall require Downstream Entities to agree that any services or other activity performed by Participating Pharmacy or Downstream Entity in accordance with this Agreement are consistent and comply with the Medicare Plan Sponsor's contractual obligations to CMS. [42 CFR 422.504(i)(3)(iii); 42 CFR 423.505(i)(3)(iii)]
6. Participating Pharmacy agrees and shall require Downstream Entities to agree that Participating Pharmacy and Downstream Entity must comply with all applicable Federal laws, regulations, and CMS instructions. [42 CFR 422.504(i)(3)(iv); 42 CFR 423.505(i)(3)(iv)]
7. Payment Provisions.
  - a. For MA-PD Plans, Medicare Plan Sponsor shall reimburse Participating Pharmacy for clean claims in accordance with the payment provisions in the reimbursement section of the Agreement. [42 CFR 422.504(c) and 42 CFR 422.520(b)(1) and (2)]
  - b. For Part D Plans, Medicare Plan Sponsor shall issue, mail, or otherwise transmit payment with respect to all clean claims, as defined below, submitted by network pharmacies (other than mail-order and long-term care pharmacies) within:
    - i. 14 days after the date on which the claim is received, for an electronic claim:  
or
    - ii. 30 days after the date on which the claim is received, for any other claim.As used in paragraph (b), a "clean claim" means a claim that has no defect or impropriety (including any lack of any required substantiating documentation) or circumstance requiring special treatment that prevents timely payment of the claim from being made under this section. A claim is considered to have been received (1) on the date on which the claim is transferred, for an electronic claim, or (2) the 5th day after the postmark day of the claim or the date specified in the time stamp of the transmission, for any other claim, whichever is sooner. [42 CFR 423.505(i)(3)(v); 423.520(a) and (b)]
8. Participating Pharmacy agrees and shall require Downstream Entities to agree to comply with the confidentiality and Member record accuracy requirements, including (1) abiding by all Federal and state laws regarding confidentiality and disclosure of medical records, or other health and enrollment information, (2) ensuring that medical information is released only in accordance with applicable Federal or state law, or pursuant to court orders or subpoenas, (3) maintaining the records and information in an accurate and timely manner, and (4) ensuring timely access by enrollees to the records and information that pertain to them. [42 CFR 422.504(a)(13) and 42 CFR 422.118; 42 CFR 423.505(b)(14); and 42 CFR 423.136]
9. With respect to MA-PD plans, Participating Pharmacy acknowledges that the Medicare Plan Sponsor oversees and is accountable to CMS for any functions and responsibilities described in Medicare Advantage regulations. [CMS Medicare Managed Care Manual, Ch. 11, s. 100.4]
10. None of Medicare Plan Sponsor's activities or responsibilities under its CMS Contract are delegated to Participating Pharmacy in this Agreement. However, if Medicare Plan Sponsor delegates its activities or responsibilities under its CMS Contract, the following requirements shall apply:
  - a. Each contract must specify delegated activities and reporting responsibilities.
  - b. Every contract must either provide for revocation of the delegation activities and reporting responsibilities described in the foregoing paragraph or specify other remedies in instances when CMS or Medicare Plan Sponsor determine that the

- parties have not performed satisfactorily.
  - c. Each contract must specify that Medicare Plan Sponsor on an ongoing basis monitors the performance of the parties.
  - d. Every contract must specify that the related entity, contractor, or subcontractor must comply with all applicable Federal laws, regulations, and CMS instructions. [42 CFR 422.504(i)(4); 42 CFR 423.505(i)(4)]
11. Pricing Source. WellDyne shall, and shall require other Medicare Plan Sponsors to:
- a. Update any prescription drug pricing standard based on the cost of the drug used for reimbursement of network pharmacies by Medicare Plan Sponsor on January 1 of each contract year and not less frequently than once every 7 days thereafter.
  - b. Indicate the source used for making any such updates; and
  - c. Disclose all individual drug prices to be updated to the applicable pharmacies in advance of their use for reimbursement of claims, if the source for any prescription drug pricing standard is not publicly available. [42 CFR 423.505(b)(21) and 505(i)(3)(vii)]
- The term “prescription drug pricing standard” means any methodology or formula for varying the pricing of a drug or drugs during the term of a pharmacy reimbursement contract that is based on the cost of a drug, which includes, but is not limited to, drug pricing references and amounts based on any of the following:
- (1) Average wholesale price.
  - (2) Wholesale acquisition cost.
  - (3) Average manufacturer price.
  - (4) Average sales price.
  - (5) Maximum allowable cost.
  - (6) Other cost, whether publicly available or not. [42 CFR 423.501]
12. Participating Pharmacy shall submit claims to Medicare Plan Sponsor or its intermediary whenever the membership ID card is presented or on file at the pharmacy unless the Member expressly requests that a particular claim not be submitted to Medicare Plan Sponsor or its intermediary. [42 CFR 423.120(c)(3)]
13. Participating Pharmacy shall submit claims via a real-time claims adjudication system. (Note: The foregoing does not apply to Participating Pharmacies operated by Indian Health Service, or Indian tribe, tribal organization, or urban Indian organization pursuant to the Indian Health Care Improvement Act.) [42 CFR 505(j) and (b)(17)]
14. The parties acknowledge and shall comply with the following: Medicare Plan Sponsor is required to provide Members with access to negotiated prices for Medicare Plan covered drugs included in the plan’s formulary. Negotiated prices must be provided even if no benefits are payable to the beneficiary for Medicare Plan covered drugs because of the application of any deductible or 100 percent coinsurance requirement following satisfaction of any initial coverage limit. Negotiated prices must be provided when the negotiated price for a Medicare Plan covered drug under Medicare Plan Sponsor’s benefit package is less than the applicable cost-sharing before the application of any deductible, before any initial coverage limit, before the annual out-of-pocket threshold, and after the annual out-of-pocket threshold. [42 CFR 423.104(g)]
- Negotiated prices means prices for Medicare Plan covered drugs that meet all the following:
- (1) Medicare Plan Sponsor (or other intermediary contracting organization) and the network dispensing pharmacy or other network dispensing provider have negotiated as the amount such network entity will receive, in total, for a particular drug.
  - (2) Are inclusive of all price concessions from network pharmacies except those contingent price concessions that cannot be determined at the point-of-sale; and
  - (3) Include any dispensing fees; but

- (4) Excludes additional contingent amounts, such as incentive fees, if these amounts increase prices and cannot be determined at the point-of-sale.
- (5) Must not be rebated back to the Medicare Plan Sponsor (or other intermediary contracting organization) in full or in part. [42 CFR 423.100]
15. Medicare Plan Sponsor and Participating Pharmacy acknowledge and shall comply with CMS requirements regarding charging/applying the correct cost sharing amount. [42 CFR 423.104]
16. Except where waived by CMS in accordance with 42 CFR 432.132(c), Participating Pharmacy shall, when dispensing a Medicare Plan covered drug, inform the Member of any differential between the price of that drug and the price of the lowest priced generic version of that Medicare Plan covered drug that is therapeutically equivalent and bioequivalent and available at that pharmacy, unless the particular Medicare Plan covered drug being purchased is the lowest-priced therapeutically equivalent and bioequivalent version of that drug available at that pharmacy. [42 CFR 432.132]
17. WellDyne may include additional requirements related to Medicare program participation in the Pharmacy Manual.

## Regulatory Exhibit 2B - Indian Health Addendum to Medicare Part D Plan Agreement

### 1. Purpose of Indian Health Addendum; Supersession.

The purpose of this Indian Health Addendum is to apply special terms and conditions to the agreement by and between WellDyne (herein "Part D Sponsor") and the participating pharmacy (herein "Provider") for administration of Medicare Prescription Drug Benefit program at pharmacies and dispensaries of Provider authorized by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, and implementing regulations in Parts 403, 411, 417, 422, and 423 of Title 42, Code of Federal Regulations. To the extent that any provision of the Part D Sponsor's agreement or any other addendum thereto is inconsistent with any provision of this Indian Health Addendum, the provisions of this Indian Health Addendum shall supersede all such other provisions.

### 2. Definitions.

For purposes of the Part D Plan Sponsor's agreement, any other addendum thereto, and this Indian Health Addendum, the following terms and definitions shall apply:

- a. The term "Part D Plan Sponsor" means a nongovernmental entity that is certified under 42 CFR 417.472, 42 CFR Part 423 or 42 CFR Part 422 as meeting the requirements and standards that apply to entities that offer Medicare Part D plans.
- b. The term "Part D Plan" means prescription drug coverage that is offered under a policy, contract, or plan that has been approved as specified in 42 CFR 423.272, 42 CFR 422.502 or 42 CFR 417.472 and that is offered by a PDP sponsor that has a contract with the Centers for Medicare and Medicaid Services that meets the contract requirements under subpart K of 42 CFR Part 423 or subpart K of 42 CFR Part 422.
- c. The term "Provider" means the Indian Health Service (IHS) and all pharmacies and dispensaries operated by the IHS, or an Indian tribe, tribal organization or urban Indian organization which operates one or more pharmacies or dispensaries and is identified by name in Section 1 of this Indian Health Addendum.
- d. The term "Centers for Medicare and Medicaid Services" means the agency of that name within the U.S. Department of Health and Human Services.
- e. The term "Indian Health Service" means the agency of that name within the U.S. Department of Health and Human Services established by Sec. 601 of the Indian Health Care Improvement Act ("IHCA"), 25 USC §1661.
- f. The term "Indian tribe" has the meaning given that term in Sec. 4 of the IHCA, 25 USC §1603.
- g. The term "tribal organization" has the meaning given that term in Sec. 4 of the IHCA, 25 USC §1603.
- h. The term "urban Indian organization" has the meaning given that term in Sec. 4 of the IHCA, 25 USC §1603.
- i. The term "Indian" has the meaning given to that term in Sec. 4 of the IHCA, 25 USC §1603.
- j. The term "dispensary" means a clinic where medicine is dispensed by a prescribing provider.

### 3. Description of Provider.

The Provider identified in Section 1 of this Indian Health Addendum is (check appropriate box):

IHS operated health care facilities located within the geographic area covered by the Provider Agreement, including hospitals, health centers and one or more pharmacies or dispensaries ("IHS Provider"). Where an IHS Provider operates more than one

pharmacy or dispensary all such pharmacies and dispensaries are covered by this Addendum.

/\_/ An Indian tribe that operates a health program, including one or more pharmacies or dispensaries, under a contract or compact with the Indian Health Service issued pursuant to the Indian Self-Determination and Education Assistance Act, 25 USC §450 et seq.

/\_/ A tribal organization authorized by one or more Indian tribes to operate a health program, including one or more pharmacies or dispensaries, under a contract or compact with the Indian Health Service issued pursuant to the Indian Self-Determination and Education Assistance Act, 25 USC §450 et seq.

/\_/ An urban Indian organization that operates a health program, including one or more pharmacies or dispensaries, under a grant from the Indian Health Service issued pursuant to Title V of the IHCA.

4. Deductibles; Annual Out-of-Pocket Threshold.

The cost of pharmaceuticals provided at a pharmacy or dispensary of Provider or paid for by the Provider through a referral to a retail pharmacy shall count toward the deductible and the annual out-of-pocket threshold applicable to an IHS beneficiary enrolled in a Part D Plan.

5. Persons eligible for services of Provider.

- a. The parties agree that the IHS Provider is limited to serving eligible IHS beneficiaries pursuant to 42 CFR Part 136 and section 813(a) and (b) of the IHCA, 25 USC §1680(a) and (b), who are also eligible for Medicare Part D services pursuant to Title XVIII, Part D of the Social Security Act and 42 CFR Part 423. The IHS Provider may provide services to non-IHS eligible persons only under certain circumstances set forth in IHCA section 813(c) and in emergencies under section 813(d) of the IHCA.
- b. The parties agree that the persons eligible for services of the Provider who is an Indian tribe or a tribal organization or a Provider who is an urban Indian organization shall be governed by the following authorities:
  - 1) Title XVIII, Part D of the Social Security Act and 42 CFR Part 423.
  - 2) IHCA sections 813, 25 USC §1680c.
  - 3) 42 CFR Part 136; and
  - 4) The terms of the contract, compact or grant issued to the Provider by the IHS for operation of a health program.
- c. No clause, term or condition of the Part D Plan Sponsor's agreement or any addendum thereto shall be construed to change, reduce, expand, or alter the eligibility of persons for services of the Provider under the Part D Plan that is inconsistent with the authorities identified in subsection (a) or (b).

6. Applicability of other Federal laws.

Federal laws and regulations affecting a Provider include but are not limited to the following:

- a. An IHS provider:
  - 1) The Anti-Deficiency Act 31 U.S.C. § 1341.
  - 2) The Indian Self Determination and Education Assistance Act ("ISDEAA"); 25 USC § 450 et seq.
  - 3) The Federal Tort Claims Act ("FTCA"), 28 U.S.C. § 2671-2680.
  - 4) The Federal Medical Care Recovery Act, 42 U.S.C. §§ 2651-2653.
  - 5) The Federal Privacy Act of 1974 ("Privacy Act"), 5 U.S.C. § 552a, 45 CFR Part 5b.
  - 6) Confidentiality of Alcohol and Drug Abuse Patient Records, 42 CFR Part 2;
  - 7) The Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), 45 CFR Parts 160 and 164; and

- 8) The IHCA, 25 U.S.C. § 1601 et seq.
  - b. A Provider who is an Indian tribe or a tribal organization:
    - 1) The ISDEAA, 25 USC §450 et seq.;
    - 2) The IHCA, 25 USC §1601, et seq.;
    - 3) The FTCA, 28 USC §§2671-2680;
    - 4) The Privacy Act, 5 USC §552a and regulations at 45 CFR Part 5b;
    - 5) The HIPAA and regulations at 45 CFR parts 160 and 164; and
    - 6) Sec. 206(e)(3) of the IHCA, 25 USC § 1624e(e)(3), regarding recovery from tortfeasors.
  - c. A Provider who is an urban Indian organization:
    - 1) The IHCA, 25 USC §1601, et seq.;
    - 2) The Privacy Act, 5 USC §552a and regulations at 45 CFR Part 5b;
    - 3) The HIPAA and regulations at 45 CFR parts 160 and 164; and
    - 4) Sec. 206(e)(3) of the IHCA, 25 USC §1621e(e)(3), regarding recovery from tortfeasors, as made applicable to urban Indian organizations by Sec. 206(i) of the IHCA.
7. Non-taxable entity.  
To the extent the Provider is a non-taxable entity, the Provider shall not be required by a Part D Plan Sponsor to collect or remit any Federal, State, or local tax.
8. Insurance and indemnification.
  - a. As an IHS provider, FTCA coverage obviates the requirement that IHS carry private malpractice insurance as the United States consents to be sued in place of federal employees for any damages to property or for personal injury or death caused by the negligence or wrongful act or omission of federal employees acting within the scope of their employment. 28 U.S.C. § 2671-2680.  
Nothing in the Part D Plan Sponsor's Agreement shall be interpreted to authorize or obligate any IHS employee to perform any act outside the scope of his/her employment. The IHS Provider shall not be required to acquire insurance, provide indemnification, or guarantee that the Plan will be held harmless from liability.
  - b. A Provider which is an Indian tribe or a tribal organization shall not be required to obtain or maintain professional liability insurance to the extent such Provider is covered by the Federal Tort Claims Act (FTCA) pursuant to Federal law (Pub.L. 101- 512, Title III, §314, as amended by Pub.L. 103-138, Title III, §308 (codified at 25 USC §450 F note); and regulations at 25 CFR Part 900, Subpt. M. To the extent a Provider that is an urban Indian organization is covered by the FTCA pursuant to section 224(g)-(n) of the Public Health Service Act, as amended by the Federally Supported Health Centers Assistance Act, Pub.L. 104-73, (codified at 42 USC §233(g)-(n)) and regulations at 42 CFR Part 6, such Provider shall not be required to obtain or maintain professional liability insurance. Further, nothing in the Part D Plan Sponsor's agreement or any addendum thereto shall be interpreted to authorize or obligate Provider or any employee of such Provider to operate outside of the scope of employment of such employee, and Provider shall not be required to indemnify the Part D Plan Sponsor.
9. Licensure.
  - a. States may not regulate the activities of IHS-operated pharmacies nor require that the IHS pharmacists be licensed in the State where they are providing services, whether the IHS employee is working at an IHS-operated facility or has been assigned to a pharmacy or dispensary of a tribe, tribal organization, or urban Indian organization. The parties agree that during the term of the Part D Plan Sponsor's Agreement, IHS pharmacists shall hold state licenses in accordance with applicable federal law, and that the IHS facilities where the

pharmacies and dispensaries are located shall be accredited in accordance with federal statutes and regulations. During the term of the Part D Plan Sponsor's Agreement, the parties agree to use the IHS facility's Drug Enforcement Agency (DEA) number consistent with federal law.

- b. Federal law (Sec. 221 of the IHClA) provides that a pharmacist employed directly by a Provider that is an Indian tribe or tribal organization is exempt from the licensing requirements of the state in which the tribal health program is located, provided the pharmacist is licensed in any state. Federal law (Sec. 408 of the IHClA) further provides that a health program operated by an Indian tribe or tribal organization shall be deemed to have met a requirement for a license under state or local law if such program meets all the applicable standards for such licensure, regardless of whether the entity obtains a license or other documentation under such state or local law. The parties agree that these federal laws apply to the Part D Plan Sponsor's Agreement and any addenda thereto. This provision shall not be interpreted to alter the requirement that a pharmacy holds a license from the Drug Enforcement Agency.
  - c. To the extent that any directly hired employee of an urban Indian Provider is exempt from State regulation, such employee shall be deemed qualified to perform services under the Part D Plan Sponsor's agreement and all addenda thereto, provided such employee is licensed to practice pharmacy in any State. Federal law (Sec. 408 of the IHClA) provides that a health program operated by an urban Indian organization shall be deemed to have met a requirement for a license under state or local law if such program meets all the applicable standards for such licensure, regardless of whether the entity obtains a license or other documentation under such state or local law. This provision shall not be interpreted to alter the requirement that a pharmacy holds a license from the Drug Enforcement Agency.
10. Provider eligibility for payments.  
To the extent that the Provider is exempt from State licensing requirements, the Provider shall not be required to hold a State license to receive any payments under the Part D Plan Sponsor's agreement and any addendum thereto.
11. Dispute Resolution.
- a. For IHS Provider. In the event of any dispute arising under the Participating Part D Plan Sponsor's Agreement or any addendum thereto, the parties agree to meet and confer in good faith to resolve any such disputes. The laws of the United States shall apply to any problem or dispute hereunder that cannot be resolved by and between the parties in good faith. Notwithstanding any provision in the Part D Plan Sponsor's Agreement or any addendum thereto to the contrary, IHS shall not be required to submit any disputes between the parties to binding arbitration.
  - b. For Tribal and Urban Providers. In the event of any dispute arising under the Participating Part D Plan Sponsor's Agreement or any addendum thereto, the parties agree to meet and confer in good faith to resolve any such disputes. Any dispute hereunder that cannot be resolved by and between the parties in good faith shall be submitted to the dispute resolution procedure pursuant to the Participating Part D Plan Sponsor's Agreement.
12. Governing Law.  
The Part D Plan Sponsor's agreement and all addenda thereto shall be governed and construed in accordance with Federal law of the United States. In the event of a conflict between such an agreement and all addenda thereto and Federal law, Federal law shall prevail. Nothing in the Part D Plan Sponsor's agreement or any addendum thereto shall

subject an Indian tribe, tribal organization, or urban Indian organization to State law to any greater extent than State law is already applicable.

13. Pharmacy/Dispensary Participation.

The Part D Plan Sponsor's agreement and all addenda thereto apply to all pharmacies and dispensaries operated by the Provider, as listed on the attached Schedule 1 to this Indian Health Addendum. A pharmacy is required to use a National Provider Identifier (NPI) number.

14. Acquisition of Pharmaceuticals.

Nothing in the Part D Plan Sponsor's agreement and all addenda thereto shall affect the Provider's acquisition of pharmaceuticals from any source, including the Federal Supply Schedule and participation in the Drug Pricing Program of Section 340B of the Public Health Service Act. Nor shall anything in such agreement and all addenda thereto require the Provider to acquire drugs from the Part D Plan Sponsor or from any other source.

15. Drug Utilization Review/Generic Equivalent Substitution.

Where the Provider lacks the capacity to comply with the information technology requirements for drug utilization review and/or generic equivalent substitution set forth in the Part D Plan Sponsor's agreement, the Provider and Part D Plan Sponsor agree that the Provider shall comply with the Part D Plan Sponsor's drug utilization review and/or generic equivalent substitution policies and procedures through an alternative method. Nothing in this paragraph shall be interpreted as waiving the applicability of the drug utilization review and/or generic equivalent substitution policies and procedures adopted by Part D sponsor in accordance with 42 C.F.R. §§ 423.153(b) and (c), as approved by CMS, to covered Part D drugs dispensed by the Provider to enrollees in the Part D Plan[s]. As specified at 42 C.F.R. §423.132(c)(3), the requirements related to notification of price differentials is waived for the Provider.

16. Claims.

The Provider may submit claims to the Part D Plan by telecommunication through an electronic billing system or by calling a toll-free number for non-electronic claims; in the case of the latter, Provider shall submit a confirmation paper claim.

17. Payment Rate.

Claims from the provider shall be paid at rates that are reasonable and appropriate.

18. Information, Outreach, and Enrollment Materials.

- a. All materials for information, outreach, or enrollment prepared for the Part D Plan shall be supplied by the Part D Plan Sponsor to Provider in paper and electronic format at no cost to the Provider.
- b. All marketing or informational material listing a provider as a pharmacy must refer to the special eligibility requirements necessary for service to be provided, consistent with the eligibility requirements as described in this Indian health addendum in paragraphs 5(a) for IHS providers and 5(b) for tribal and urban providers.

19. Hours of Service.

The hours of service of the pharmacies or dispensaries of Provider shall be established by Provider. At the request of the Part D Plan Sponsor, Provider shall provide written notification of its hours of service.

20. Endorsement.

An endorsement of a non-Federal entity, event, product, service, or enterprise may be neither stated nor implied by the IHS provider or IHS employees in their official capacities and titles. Such agency names and positions may not be used to suggest official endorsement or preferential treatment of any non-Federal entity under this agreement.

21. Sovereign Immunity

Nothing in the Part D Plan Sponsor's Agreement or in any addendum thereto shall a waiver of federal or tribal sovereign immunity.

## Regulatory Exhibit 3 - LTC Pharmacy Part D

Provisions of this Exhibit apply to Participating Pharmacies that are long term care (“LTC”) pharmacies participating in Medicare Plans and control over any conflicting provisions in the Agreement.

1. Additional Definitions.
  - a. “CMS” means Centers for Medicare and Medicaid Services within HHS.
  - b. “CMS Contract” means the contract between CMS and the Medicare Plan Sponsor.
  - c. The term “date of completion of an audit” means the completion of audit by HHS, the Government Accountability Office, or their designees, or a Medicare Plan Sponsor, or Medicare Plan Sponsor contractor or related entity.
  - d. “Downstream Entity” for purposes of this Exhibit means a contractor of Participating Pharmacy providing products or services covered under a Medicare Part D or MA-PD Plan to Medicare Members.
  - e. The term “final date of the contract period” means the final term of the CMS Contract.
  - f. As used herein, “long term care facility” means a skilled nursing facility as defined in section 1819(a) of the Social Security Act, or a medical institution or nursing facility for which payment is made for an institutionalized individual under section 1902(q)(1)(B) of the Social Security Act. [42 CFR 423.100]
  - g. “HHS” means U.S. Department of Health and Human Services.
  - h. “MA-PD plan” means a Medicare Part C plan with Part D benefits.
  - i. “Medicare Plan” means a Part D plan or MA-PD plan.
  - j. “Medicare Plan Sponsor” means WellDyne or a plan sponsor of a Medicare Plan contracted with WellDyne to manage pharmacy benefits.
  - k. “Part D plan” means a prescription drug plan under Medicare Part D.
  - l. “Member” means a member enrolled in a Medicare Plan.
2. Participating Pharmacy agrees and shall require Downstream Entities to agree that:
  - a. HHS, the Comptroller General, or their designees have the right to audit, evaluate, collect, and inspect any books, contracts, computer, or other electronic systems, including medical records and documentation of Participating Pharmacy, Downstream Entity and related entities related to the CMS Contract.
  - b. HHS, the Comptroller General or their designees have the right to audit, evaluate, collect, and inspect any records under this section directly from Participating Pharmacy or Downstream Entity.
  - c. For records subject to review under the foregoing paragraph of this section, except in exceptional circumstances, CMS will provide notification to the Medicare Plan Sponsor that a direct request for information has been initiated.
  - d. HHS, the Comptroller General’s, or their designee’s right to inspect, evaluate, and audit any pertinent information for any particular contract period exists through 10 years from the final date of the contract period or from the date of completion of an audit, whichever is later. [42 CFR 422.504(i)(2); 42 CFR 423.505(i)(2)]
3. Participating Pharmacy and Downstream Entity shall not hold a Member liable for fees that are the obligation of the Medicare Plan Sponsor. [42 CFR 422.504(i)(3)(i) and 422.504(g)(1)(i); 42 CFR 423.505(i)(3)(i) and 422.505(g)(1)(i)]
4. For MA-PD plans with Members eligible for both Medicare and Medicaid, such Members will not be held liable for Medicare Part A and B cost sharing when the state is responsible for paying such amounts. Participating Pharmacy shall be informed of Medicare and Medicaid benefits, and rules for Members eligible for Medicare and

Medicaid. Medicare Plan Sponsors of MA-PD Plans may not impose cost-sharing that exceeds the amount of cost-sharing that would be permitted with respect to the individual under title XIX (Medicaid) if the individual were not enrolled in such a plan. Participating Pharmacy will (a) accept the WellDyne payment under this Agreement as payment in full, or (b) bill the appropriate state source. [42 CFR 422.504(g)(3)(iii)]

5. Participating Pharmacy agrees and shall require Downstream Entities to agree that any services or other activity performed by Participating Pharmacy or Downstream Entity in accordance with this Agreement are consistent and comply with the Medicare Plan Sponsor's contractual obligations to CMS. [42 CFR 422.504(i)(3)(iii); 42 CFR 423.505(i)(3)(iii)]
6. Participating Pharmacy agrees and shall require Downstream Entities to agree that Participating Pharmacy and Downstream Entity must comply with all applicable Federal laws, regulations, and CMS instructions. [42 CFR 422.504(i)(3)(iv); 42 CFR 423.505(i)(3)(iv)]
7. Payment Provisions.
  - a. Medicare Plan Sponsor shall reimburse Participating Pharmacy for clean claims in accordance with the payment provisions in the reimbursement section of the Agreement. [42 CFR 422.504(c) and 42 CFR 422.520(b)(1) and (2)]
  - b. Long term care pharmacies located in, or having a contract with, a long-term care facility shall have not less than 30 days, nor more than 90 days, to submit to the Medicare Plan Sponsor claims for reimbursement under the plan. [42 CFR 423.505(b)(20)]
8. Participating Pharmacy agrees and shall require Downstream Entities to agree to comply with the confidentiality and Member record accuracy requirements, including (1) abiding by all Federal and state laws regarding confidentiality and disclosure of medical records, or other health and enrollment information, (2) ensuring that medical information is released only in accordance with applicable Federal or state law, or pursuant to court orders or subpoenas, (3) maintaining the records and information in an accurate and timely manner, and (4) ensuring timely access by enrollees to the records and information that pertain to them. [42 CFR 422.504(a)(13) and 42 CFR 422.118; 42 CFR 423.505(b)(14); and 42 CFR 423.136]
9. With respect to MA-PD Plans, Participating Pharmacy acknowledges that the Medicare Plan Sponsor oversees and is accountable to CMS or any functions and responsibilities described in Medicare Advantage regulations. [CMS Medicare Managed Care Manual, Ch. 11, s. 100.4]
10. None of Medicare Plan Sponsor's activities or responsibilities under its CMS Contract are delegated to Participating Pharmacy in this Agreement. However, if Medicare Plan Sponsor delegates its activities or responsibilities under its CMS Contract, the following requirements shall apply:
  - a. Each contract must specify delegated activities and reporting responsibilities.
  - b. Every contract must either provide for revocation of the delegation activities and reporting responsibilities described in the foregoing paragraph or specify other remedies in instances when CMS or Medicare Plan Sponsor determine that the parties have not performed satisfactorily.
  - c. Each contract must specify that Medicare Plan Sponsor on an ongoing basis monitors the performance of the parties.
  - d. Every contract must specify that the related entity, contractor, or subcontractor must comply with all applicable Federal laws, regulations, and CMS instructions. [42 CFR 422.504(i)(4); 42 CFR 423.505(i)(4)]
11. Pricing Source. WellDyne shall, and shall require other Medicare Plan Sponsors to:
  - a. Update any prescription drug pricing standard based on the cost of the drug used for reimbursement of network pharmacies by Medicare Plan Sponsor on January

- 1 of each contract year and not less frequently than once every 7 days thereafter.
- b. Indicate the source used for making any such updates; and
  - c. Disclose all individual drug prices to be updated to the applicable pharmacies in advance of their use for reimbursement of claims, if the source for any prescription drug pricing standard is not publicly available. [42 CFR 423.505(b)(21) and 505(i)(3)(vii)]  
 The term “prescription drug pricing standard” means any methodology or formula for varying the pricing of a drug or drugs during the term of a pharmacy reimbursement contract that is based on the cost of a drug, which includes, but is not limited to, drug pricing references and amounts based on any of the following:
    - (1) Average wholesale price.
    - (2) Wholesale acquisition cost.
    - (3) Average manufacturer price.
    - (4) Average sales price.
    - (5) Maximum allowable cost.
    - (6) Other cost, whether publicly available or not. [42 CFR 423.501]
12. Participating Pharmacy shall submit claims to Medicare Plan Sponsor or its intermediary whenever the membership ID card is presented or on file at the pharmacy unless the Member expressly requests that a particular claim not be submitted to Medicare Plan Sponsor or its intermediary. [42 CFR 423.120(c)(3)]
  13. Participating Pharmacy shall submit claims via a real-time claims adjudication system. (Note: The foregoing does not apply to Participating Pharmacies operated by Indian Health Service, or Indian tribe, tribal organization, or urban Indian organization pursuant to the Indian Health Care Improvement Act.) [42 CFR 505(j) and (b)(17)]
  14. The parties acknowledge and shall comply with the following: Medicare Plan Sponsor is required to provide Members with access to negotiated prices for Medicare Plan covered drugs included in the plan’s formulary. Negotiated prices must be provided even if no benefits are payable to the beneficiary for Medicare Plan covered drugs because of the application of any deductible or 100 percent coinsurance requirement following satisfaction of any initial coverage limit. Negotiated prices must be provided when the negotiated price for a Medicare Plan covered drug under Medicare Plan Sponsor’s benefit package is less than the applicable cost-sharing before the application of any deductible, before any initial coverage limit, before the annual out-of-pocket threshold, and after the annual out-of-pocket threshold. [42 CFR 423.104(g)]  
 Negotiated prices means prices for Medicare Plan covered drugs that meet all the following:
    - (1) Medicare Plan Sponsor (or other intermediary contracting organization) and the network dispensing pharmacy or other network dispensing provider have negotiated as the amount such network entity will receive, in total, for a particular drug.
    - (2) Are inclusive of all price concessions from network pharmacies except those contingent price concessions that cannot be determined at the point-of-sale; and
    - (3) Include any dispensing fees; but
    - (4) Excludes additional contingent amounts, such as incentive fees, if these amounts increase prices and cannot be determined at the point-of-sale.
    - (5) Must not be rebated back to the Medicare Plan Sponsor (or other intermediary contracting organization) in full or in part. [42 CFR 423.100]
  15. Medicare Plan Sponsor and Participating Pharmacy acknowledge and shall comply with CMS requirements regarding charging/applying the correct cost sharing amount. [42 CFR 423.104]
  16. Except where waived by CMS in accordance with 42 CFR 432.132(c), Participating Pharmacy shall, when dispensing a Medicare Plan covered drug, inform the Member of

any differential between the price of that drug and the price of the lowest priced generic version of that Medicare Plan covered drug that is therapeutically equivalent and bioequivalent and available at that pharmacy, unless the particular Medicare Plan covered drug being purchased is the lowest-priced therapeutically equivalent and bioequivalent version of that drug available at that pharmacy. [42 CFR 432.132]

17. Appropriate Dispensing of Prescription Drugs in LTC Facilities under Part D and MA-PD Plans.
- a. When dispensing Medicare Plan covered drugs to Members who reside in long-term care facilities, Medicare Plan Sponsor must:
    - i. Require Participating Pharmacies servicing long term care facilities to:
      - 1. Dispense solid oral doses of brand-name drugs to Members in such facilities in no greater than 14-day increments at a time. For purposes of this section only “brand name drug” means a drug for which an application is approved under section 505(c) of the Federal Food, Drug, and Cosmetic Act (21 USC 355(c)), including an application referred to in section 505(b)(2) of the Federal Food, Drug and Cosmetic Act (21 USC 355(b)(2)).
      - 2. Permit the use of uniform dispensing techniques for Medicare Plan covered drugs dispensed to Members in such facilities as defined by each of the long-term care facilities in which such Members reside; and
    - ii. Not penalize long-term care facilities’ choice of more efficient uniform dispensing techniques described in paragraph b of this section by prorating dispensing fees based on days’ supply or quantity dispensed.
    - iii. Ensure that any difference in payment methodology among long-term care pharmacies incentivizes more efficient dispensing techniques.
    - iv. Collect and report information, in a form and manner specified by CMS, on the dispensing methodology used for each dispensing event in respect of dispensing Medicare Plan covered drug to Members who reside in long-term care facilities, and Participating Pharmacy shall cooperate and participate in such activity.
  - b. Exclusions. CMS excludes from the requirements under paragraph (a) of this section:
    - i. Solid oral doses of antibiotics; or
    - ii. Solid oral doses that are dispensed in their original container as indicated in the Food and Drug Administration Prescribing Information or are customarily dispensed in their original packaging to assist patients with compliance (for example, oral contraceptives).
  - c. Waivers. CMS waives the requirements under paragraph (a) of this section, except paragraphs (a)(ii) and (iii), for pharmacies when they service intermediate care facilities for the mentally retarded (ICFs/IID) and institutes for mental disease (IMDs) as defined in 42 CFR 435.1010 and for I/T/U pharmacies (as defined in 42 CFR 423.100).
  - d. Unused drugs returned to the pharmacy. Plan Sponsor shall include in the Pharmacy Manual provisions that address the disposal of drugs that have been dispensed to a Member in a long-term care facility but not used and which have been returned to the pharmacy, in accordance with Federal and state regulations, as well as whether return for credit and reuse is authorized where permitted under state law.
18. WellDyne may include additional requirements related to Medicare program participation in the Pharmacy Manual.

## Appendix C MAC State-Specific Requirements

**Indiana** — For a MAC Appeal, Network Pharmacy Provider must obtain, fully complete, and submit the MAC Form to WellDyne within sixty (60) calendar days from the date of the initial Claim submission. WellDyne will investigate and resolve the MAC Appeal within thirty (30) calendar days after the completed MAC Form is received by WellDyne. If the MAC Appeal is resolved in favor of the Network Pharmacy Provider, WellDyne will change the MAC of the drug for the Network Pharmacy Provider that filed the appeal as of the initial date of service that the appealed Claim was dispensed, and adjust the MAC of the drug for all other Network Pharmacy Providers in this state within the network that filled a prescription for patients covered under the same health plan beginning on the initial date of service the appealed drug was dispensed. WellDyne will provide notice to all other contracted Network Pharmacy Providers that an appeal has been upheld and will permit the challenging Network Pharmacy Provider and all other Network Pharmacy Providers that filled the prescriptions for patients covered under the same health plan to reverse/resubmit. If WellDyne upholds the MAC Pricing of the particular Covered Prescription Service Drug Product at issue, WellDyne shall provide Network Pharmacy Provider the reason for the denial of the MAC Appeal and identify the NDC of a Drug Product which may be purchased by Network Pharmacy Provider at a price at or below the MAC price determined by WellDyne and provide the name of the referenced national or regional pharmaceutical wholesaler, operating in Indiana. Within ten (10) calendar days after a request from Network Pharmacy Provider, WellDyne will provide a current list of the sources used to determine MAC pricing. Network Pharmacy Provider may request a current list of the sources used to determine MAC pricing by submitting a request via email to [RetailManager@netcardsystems.com](mailto:RetailManager@netcardsystems.com). WellDyne will publish every 7 days an update to the MAC List Pricing online at <https://www.welldyne.com/for-pharmacies/>

**Oregon** — For a MAC Appeal, Network Pharmacy Provider must obtain, fully complete, and submit the MAC Form to WellDyne within sixty (60) calendar days following the reimbursement of the initial Claim. WellDyne will investigate and resolve the MAC Appeal within seven (7) business days after the completed MAC Form is received by WellDyne. If the MAC Appeal is resolved in favor of the Network Pharmacy Provider, WellDyne will adjust the MAC for the drug as of the date of the original claim for payment, as well as make the adjustment applicable to all similarly situated Network Pharmacy Providers in this state within the network. WellDyne will reprocess and adjust reimbursement for the claim in question without charging any adjudication fees. If WellDyne upholds the MAC Pricing of the particular Covered Prescription Service Drug Product at issue, WellDyne shall provide Network Pharmacy Provider the reason for the denial of the MAC Appeal and identify the NDC of a Drug Product which may be purchased by Network Pharmacy Provider at a price at or below the MAC price determined by WellDyne