



VYTL  **ONE**
SPECIALTY PHARMACY

Welcome Packet

Your guide to helpful resources, support,
and everything you need to get started.

Enrollee name: _____(optional)

Drug and prescription number: _____(optional)

Medicare Drug Coverage and Your Rights

You have the right to ask for a coverage determination from your Medicare drug plan to provide or pay for a drug you think should be covered, provided, or continued. You also have the right to ask for a special type of coverage determination called an **“exception”** if you:

- Need a drug that’s not on your plan’s list of covered drugs
- Believe a coverage rule (like prior authorization or a quantity limit) shouldn’t apply to you for medical reasons
- Need to take a non-preferred drug and you want the plan to cover the drug at a preferred drug price

How to ask for a coverage determination

To ask for a coverage determination, you or your prescriber can call your Medicare drug plan’s toll-free phone number on the back of your plan membership card, or go to your plan’s website. You can ask for an expedited (24 hour) decision if your health could be seriously harmed by waiting up to 72 hours for a decision.

Be ready to tell your Medicare drug plan:

- The name of the prescription drug, including dose and strength (if known)
- The name of the pharmacy that tried to fill the prescription
- The date you tried to fill the prescription
- If you ask for an exception, your prescriber will need to explain why you need the off-formulary or non-preferred drug, or why a coverage rule shouldn’t apply to you

Your Medicare drug plan will send you a written decision. If coverage isn’t approved and you disagree with this decision, you have the right to appeal. The plan’s notice will explain why coverage was denied and how to ask for an appeal.

Get help and more information

Look at your plan materials or call 1-800-MEDICARE (1-800-633-4227) for more information about how to ask for a coverage determination. TTY users can call 1-877-486-2048. For help contacting your plan, call 1-800-MEDICARE.

To get this form in an accessible format (like large print, Braille, or audio) contact your Medicare drug plan. You also have the right to file a complaint if you feel you've been discriminated against. Visit [Medicare.gov/about-us/accessibility-nondiscrimination-notice](https://www.medicare.gov/about-us/accessibility-nondiscrimination-notice), or call 1-800-MEDICARE (1-800-633-4227) for more information. TTY users can call 1-877-486-2048.

PRA Disclosure Statement According to the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0938-0975. This information collection is used to provide notice to enrollees about how to contact their Part D plan to request a coverage determination. The time required to complete this information collection is estimated to average 1 minute per response, including the time to review instructions, search existing data resources, gather the data needed, to review and complete the information collection. This information collection is required under § 423.562(a)(3) and an associated regulatory provision at § 423.128(b)(7)(iii). If you have comments concerning the accuracy of the time estimate(s) or suggestions for improving this form, please write to: CMS, 7500 Security Boulevard, Attn: PRA Reports Clearance Officer, Mail Stop C4-26-05, Baltimore, Maryland 21244-1850.

MEDICARE DMEPOS SUPPLIER STANDARDS

Note: This is an abbreviated version of the supplier standards every Medicare DMEPOS supplier must meet in order to obtain and retain their billing privileges. These standards, in their entirety, are listed in 42 C.F.R. 424.57(c).

1. A supplier must be in compliance with all applicable Federal and State licensure and regulatory requirements.
2. A supplier must provide complete and accurate information on the DMEPOS supplier application. Any changes to this information must be reported to the National Supplier Clearinghouse within 30 days.
3. A supplier must have an authorized individual (whose signature is binding) sign the enrollment application for billing privileges.
4. A supplier must fill orders from its own inventory, or contract with other companies for the purchase of items necessary to fill orders. A supplier may not contract with any entity that is currently excluded from the Medicare program, any State health care programs, or any other Federal procurement or non-procurement programs.
5. A supplier must advise beneficiaries that they may rent or purchase inexpensive or routinely purchased durable medical equipment, and of the purchase option for capped rental equipment.
6. A supplier must notify beneficiaries of warranty coverage and honor all warranties under applicable State law, and repair or replace free of charge Medicare covered items that are under warranty.
7. A supplier must maintain a physical facility on an appropriate site and must maintain a visible sign with posted hours of operation. The location must be accessible to the public and staffed during posted hours of business. The location must be at least 200 square feet and contain space for storing records.
8. A supplier must permit CMS or its agents to conduct on-site inspections to ascertain the supplier's compliance with these standards.
9. A supplier must maintain a primary business telephone listed under the name of the business in a local directory or a toll free number available through directory assistance. The exclusive use of a beeper, answering machine, answering service or cell phone during posted business hours is prohibited.
10. A supplier must have comprehensive liability insurance in the amount of at least \$300,000 that covers both the supplier's place of business and all customers and employees of the supplier. If the supplier manufactures its own items, this insurance must also cover product liability and completed operations.
11. A supplier is prohibited from direct solicitation to Medicare beneficiaries. For complete details on this prohibition see 42 CFR§424.57 (c) (11).
12. A supplier is responsible for delivery of and must instruct beneficiaries on the use of Medicare covered items, and maintain proof of delivery and beneficiary instruction.
13. A supplier must answer questions and respond to complaints of beneficiaries, and maintain documentation of such contacts.
14. A supplier must maintain and replace at no charge or repair cost either directly, or through a service contract with another company, any Medicare-covered items it has rented to beneficiaries.
15. A supplier must accept returns of substandard (less than full quality for the particular item) or unsuitable items (inappropriate for the beneficiary at the time it was fitted and rented or sold) from beneficiaries.



16. A supplier must disclose these standards to each beneficiary it supplies a Medicare-covered item.
17. A supplier must disclose any person having ownership, financial, or control interest in the supplier.
18. A supplier must not convey or reassign a supplier number; i.e., the supplier may not sell or allow another entity to use its Medicare billing number.
19. A supplier must have a complaint resolution protocol established to address beneficiary complaints that relate to these standards. A record of these complaints must be maintained at the physical facility.
20. Complaint records must include: the name, address, telephone number and health insurance claim number of the beneficiary, a summary of the complaint, and any actions taken to resolve it.
21. A supplier must agree to furnish CMS any information required by the Medicare statute and regulations.
22. All suppliers must be accredited by a CMS-approved accreditation organization in order to receive and retain a supplier billing number. The accreditation must indicate the specific products and services, for which the supplier is accredited in order for the supplier to receive payment for those specific products and services (except for certain exempt pharmaceuticals).
23. All suppliers must notify their accreditation organization when a new DMEPOS location is opened.
24. All supplier locations, whether owned or subcontracted, must meet the DMEPOS quality standards and be separately accredited in order to bill Medicare.
25. All suppliers must disclose upon enrollment all products and services, including the addition of new product lines for which they are seeking accreditation.
26. A supplier must meet the surety bond requirements specified in 42 CFR § 424.57 (d).
27. A supplier must obtain oxygen from a state-licensed oxygen supplier.
28. A supplier must maintain ordering and referring documentation consistent with provisions found in 42 CFR § 424.516(f).
29. A supplier is prohibited from sharing a practice location with other Medicare providers and suppliers.
30. A supplier must remain open to the public for a minimum of 30 hours per week except physicians (as defined in section 1848(j) (3) of the Act) or physical and occupational therapists or a DMEPOS supplier working with custom made orthotics and prosthetics.

DMEPOS suppliers have the option to disclose the following statement to satisfy the requirement outlined in Supplier Standard 16 in lieu of providing a copy of the standards to the beneficiary.

The products and/or services provided to you by (supplier legal business name or DBA) are subject to the supplier standards contained in the Federal regulations shown at 42 Code of Federal Regulations Section 424.57(c). These standards concern business professional and operational matters (e.g. honoring warranties and hours of operation). The full text of these standards can be obtained at <http://www.ecfr.gov>. Upon request we will furnish you a written copy of the standards.



NOTICE OF PRIVACY PRACTICES – PROTECTED HEALTH INFORMATION

THIS NOTICE DESCRIBES HOW MEDICAL INFORMATION ABOUT YOU MAY BE USED AND DISCLOSED AND HOW YOU CAN GET ACCESS TO THIS INFORMATION. PLEASE REVIEW IT CAREFULLY.

In accordance with the requirements of the Health Insurance Portability and Accountability Act of 1996 (“HIPAA”), the organization is required to inform you of its practices in relation to the protected health information that it maintains about you. HIPAA mandates minimum standards that a covered entity such as the organization must maintain in relation to your protected health information. This Notice of Privacy Practices is being provided to help you understand how the organization meets these minimum standards. It is also meant to inform you of the ways that the organization may use the personal information it collects about you and how it may disclose it.

UNDERSTANDING YOUR PROTECTED HEALTH INFORMATION

When you receive care from a healthcare provider, a record of that treatment is made. This record will typically contain information on your diagnosis, treatment, and future plan of treatment and is often collectively referred to as your medical record. This medical record includes protected health information and lays the foundation for determining your plan of care and treatment and allows for a successful means of communication between all healthcare professionals that contribute to your care.

HIPAA protects information found in your medical record from use or disclosure without your authorization. The information protected by HIPAA includes:

1. Any information related to your past, present or future physical or mental health;
2. The past, present or future payment for health services you have received;
3. The specific care that you have received, are receiving or will receive;
4. Any information that identifies you as the individual receiving the care;
5. Any information that someone could reasonably use to identify you as receiving the care; and
6. Any genetic information about an individual for underwriting purposes.

This information is referred to as protected health information throughout this Notice.

TREATMENT, PAYMENT AND HEALTHCARE OPERATIONS

As a Covered Entity, the organization is required to inform you of how it may use your protected health information. In providing treatment to you, the organization will use your protected health information for the purposes of treatment, payment and healthcare operations.

Treatment - As it pertains to the organization, treatment means providing to you drugs, medications, supplies and durable medical equipment services as ordered by your physician. Treatment also includes coordination and consultation with your physician and other health care providers. As the organization provides these services to you, information obtained during this process will be recorded in your medical record. The organization will use this information, in coordination with your physician, to determine the best course of treatment for you.



Payment - Payment purposes consist of activities required to obtain reimbursement from your insurance carrier for the services ordered by your physician and provided to you by the organization. This includes, but is not limited to, copay assistance, eligibility determination, pre-certification, billing and collection activities, obtaining documentation required by your insurer, and when applicable, disclosure of limited information to consumer reporting agencies.

Healthcare operations - Operations can include, but are not limited to, review of your protected health information by members of the organization's professional healthcare staff to ensure compliance with all federal and state regulations. This information will then be utilized to continually improve the quality and effectiveness of the services provided to you by the organization. Healthcare operations also include the organization's business management and general administrative activities.

OTHER USES AND DISCLOSURES

Under HIPAA, there are a limited number of other uses and disclosures of protected health information that do not require a specific authorization from you. The organization may in the following circumstances disclose your protected health information.

1. The organization may disclose limited health information about you to notify local agencies (i.e. power, gas, phone company, and emergency medical services), in the event of an emergency (i.e. flood, hurricanes, etc.), of your need for life sustaining equipment or assistance in evacuation due to your medical condition.
2. The organization may disclose to a member of your family, other relative, or a close personal friend, or any other person identified by you, the protected health information directly relevant to such person's involvement with your care or payment related to your health care.
3. The organization may disclose protected health information to others as required by law.
4. The organization may disclose protected health information for certain public health activities and purposes.
5. The organization may disclose protected health information to a legally-authorized government authority, such as a social service or protective services agency, if we reasonably believe you are a victim of abuse, neglect or domestic violence.
6. The organization may disclose protected health information for law enforcement purposes and in response to court orders or subpoenas.
7. The organization may disclose protected health information to agencies authorized by law to conduct health oversight activities, including audits, investigations, licensing and similar activities.
8. The organization may disclose protected health information to attorneys, accountants, and others acting on behalf of the organization to respond to lawsuits and legal actions, provided they have signed written contracts agreeing to safeguard the confidentiality of the information.
9. The organization may disclose protected health information to the Secretary of the Department of Health and Human Services for HIPAA compliance and enforcement purposes.
10. The organization may disclose protected health information to perform health research.



11. The organization may disclose protected health information to respond to organ and tissue donation requests.
12. The organization may disclose protected health information to work with a medical examiner or funeral director.
13. The organization may disclose protected health information to address workers' compensation, law enforcement and other government requests.

In order to release information contained in your medical record for purposes other than treatment, payment or healthcare operations, or as otherwise described herein, the organization must obtain a specific signed authorization from you. Those uses or disclosures requiring your authorization include the following records and purposes: psychotherapy notes unless the use or disclosure is otherwise permitted or required by law, marketing purposes, or the sale of your protected health information. You may revoke such authorization at any time by giving notice to the Privacy Officer, as described herein, except to the extent the organization has taken action in reliance on the authorization, and provided that any information disclosed prior to such revocation has the potential to be subject to redisclosure by the recipient and no longer protected by HIPAA.

PART 2 SUBSTANCE USE DISORDER TREATMENT RECORDS

Although we are not a substance use disorder program, we may receive information about you from a substance use disorder treatment program that is covered by 42 CFR Part 2 (a "Part 2 Program"). If the organization receives or maintains such information from a Part 2 Program through a general consent you provide to the Part 2 Program to use and disclose the Part 2 Program record for purposes of treatment, payment, or health care operations, it may use and disclose your Part 2 Program record for treatment, payment, and health care operations purposes as described in this Notice of Privacy Practices. If the organization receives or maintains such information through specific consent you provide to the organization or another third party, we will use and disclose your Part 2 Program record only as expressly permitted by you in your consent provided to the organization. The organization may not use or disclose such Part 2 Program records, or provide testimony relaying the content of such records, in a civil, criminal, administrative, or legislative proceeding against you unless it has your written consent or a court order after notice and an opportunity to be heard is provided to you or the holder of the record as provided in Part 2. A court order authorizing use or disclosure must be accompanied by a subpoena or other legal requirement compelling disclosure before the requested record is used or disclosed.

YOUR RIGHTS AS A PATIENT OF THE ORGANIZATION

In accordance with HIPAA you have the following rights in relation to your protected health information.



1. You have the right of access to inspect and obtain a copy of your medical record in a timely manner, subject to certain limitations.
2. You have the right to obtain an accounting of disclosures of your medical record for purposes other than treatment, payment and healthcare operations.
3. You have the right to request communications of your medical record by alternative means (i.e. electronically or summary) or at alternative locations.
4. You may request, in writing, additional restrictions on certain uses or disclosures of your protected health information; however, the organization is not required to agree to the requested restrictions.
5. You have the right to receive confidential communications of protected health information.
6. You have the right to request amendments to your medical record to the extent that you believe any information is incorrect or incomplete; however, the organization is not required to agree to the requested amendments.
7. You have the right to obtain a copy of this Notice of Privacy Practices. You can ask for a paper copy of this notice at any time, even if you have agreed to receive the notice electronically.
8. You have the right to file a complaint if you feel your rights are violated, as described herein.

RESPONSIBILITIES OF THE ORGANIZATION

In accordance with HIPAA, the organization is required to:

1. Maintain the confidentiality of your protected health information. Your state laws may provide more protection than the federal laws and, in that case, we will abide by the more restrictive statute.
2. Provide you with notice of our legal obligations and privacy practices regarding information it may accumulate about you and is obligated to abide by the terms of this notice currently in effect.
3. Notify you if it is unable to agree to a requested restriction, and make every effort to accommodate reasonable requests for communication of health information by alternative means.
4. Post its Notice of Privacy Practices on its website.
5. Notify affected individuals of any unauthorized acquisition, access, use, or disclosure of unsecured PHI without unreasonable delay but not later than 60 calendar days after discovery.

Please be advised that in addition to these responsibilities, the organization reserves the right to change the terms of its Notice of Privacy Practices and make those changes applicable to all protected health information maintained at that time. If there is a change to its Notice of Privacy Practices, we will communicate revisions to this Notice through our website <https://vytlone.com/hipaa/>.

FOR MORE INFORMATION OR TO REPORT A PROBLEM





If you have questions, would like additional information or, if you suspect misuse of your protected health information and believe that your rights have been violated, you may, without fear of retaliation, contact:

Privacy Officer
320 South Polk Street, Suite 200
Amarillo, TX 79101
1 (800) 658-6146

Or

The Office for Civil Rights
U.S. Department of Health & Human Services
200 Independence Avenue SW
Room 509F HHH Building
Washington D.C. 20201
1-877-696-6775
www.hhs.gov/ocr/privacy/hipaa/complaints/



PATIENT RIGHTS & RESPONSIBILITY

To ensure the finest care possible, as a patient receiving our pharmacy services, you should understand your role, rights and responsibilities involved in your plan of care.

Patient Rights

1. To select those who provide you with pharmacy services
2. To receive the appropriate or prescribed services in a professional manner without discrimination relative to your age, sex, race, religion, ethnic origin, sexual preference or physical or mental handicap
3. To be treated with friendliness, courtesy and respect by each and every individual representing our pharmacy, who provided treatment or services for you and be free from neglect or abuse, be it physical or mental
4. To assist in the development and preparation of your plan of care that is designed to satisfy, as best as possible, your current needs
5. To be provided with adequate information from which you can give your informed consent for commencement of services, the continuation of services, the transfer of services to another health care provider, or the termination of services
6. To request and receive complete and up-to-date information relative to your condition, treatment, alternative treatments, risk of treatment or care plans
7. To receive treatment and services within the scope of your plan of care, promptly and professionally, while being fully informed as to our pharmacy's policies, procedures and charges
8. To request and receive data regarding treatment, services, or costs
9. To be given information as it relates to the uses and disclosure of your plan of care
10. To have your plan of care remain private and confidential, except as required and permitted by law
11. To receive instructions on handling drug recall
12. To confidentiality and privacy of all information contained in the client/patient record and of Protected Health Information; PHI will only be shared with the Patient Management Program in accordance with state and federal law
13. To receive information on how to access support from consumer advocates groups
14. To receive pharmacy health and safety information to include consumers rights and responsibilities
15. To know about philosophy and characteristics of the patient management program
16. To identify the program's staff members, including the program and their job title, and to speak with a supervisor of the staff member's supervisor if requested
17. To speak to a healthcare professional
18. To receive information about the patient management program
19. To receive administrative information regarding changes in or termination of the patient management program
20. To decline participation, revoke consent or dis-enroll at any point in time



21. To be fully informed in advance about care/service to be provided, including the disciplines that furnish care and the frequency of visits, as well as any modifications to the plan of care
22. To be informed, both orally and in writing, in advance of care being provided, of the charges, including payment for care/service expected from third parties and any charges for which the client/patient will be responsible
23. To receive information about the scope of services that the organization will provide and specific limitations on those services
24. To participate in the development and periodic revision of the plan of care
25. To refuse care or treatment after the consequences of refusing care or treatment are fully presented
26. To be informed of client/patient rights under state law to formulate an Advanced Directive, if applicable
27. To have one's property and person treated with respect, consideration, and recognition of client/patient dignity and individuality
28. To be able to identify visiting personnel members through proper identification
29. To be free from mistreatment, neglect, or verbal, mental, sexual, and physical abuse, including injuries of unknown source, and misappropriation of client/patient property
30. To voice grievances/complaints regarding treatment or care, lack of respect of property or recommend changes in policy, personnel, or care/service without restraint, interference, coercion, discrimination, or reprisal
31. To have grievances/complaints regarding treatment or care that is (or fails to be) furnished, or lack of respect of property investigated
32. To be advised on agency's policies and procedures regarding the disclosure of clinical records
33. To choose a health care provider, including choosing an attending physician, if applicable
34. To receive appropriate care without discrimination in accordance with physician orders, if applicable
35. To be informed of any financial benefits when referred to an organization
36. To be fully informed of one's responsibilities
37. To receive information to assist in interactions with the organization
38. To receive information about an order delay, and assistance in obtaining the medication elsewhere, if necessary.

Patient Responsibilities

1. To provide accurate and complete information regarding your past and present medical history
2. To agree to a schedule of services and report any cancellation of scheduled appointments and/or treatments
3. To participate in the development and updating of a plan of care
4. To communicate whether you clearly comprehend the course of treatment and plan of care
5. To comply with the plan of care and clinical instructions



6. To accept responsibility for your actions, if refusing treatment or not complying with, the prescribed treatment and services
7. To respect the rights of pharmacy personnel
8. To notify your Physician and the Pharmacy with any potential side effects and/or complications
9. To notify Maxor Specialty Pharmacy via telephone when medication supply is running low so refill maybe shipped to you promptly
10. To submit any forms that are necessary to participate in the program to the extent required by law
11. To give accurate clinical and contact information and to notify the patient management program of changes in this information
12. To notify their treating provider of their participation in the patient management program, if applicable
13. To maintain any equipment provided
14. To submit forms that are necessary to receive services
15. To notify the treating provider of participation in the services provided by the pharmacy
16. To notify the pharmacy of any concerns about the care or services provided.



