

**STATE OF VERMONT  
AGENCY OF HUMAN SERVICES  
Office of Vermont Health Access (OVHA)**

**AHS Bulletin No: 09-25E**

Secretary of State's ID Number: 09E-015

**FROM:** Susan Besio, Ph.D., Director  
Office of Vermont Health Access

**DATE:** 11/10/09

**SUBJECT:** State Fiscal Year 2010 Coverage Changes - 90-day Maintenance Fills

**CHANGES ADOPTED EFFECTIVE:** 11/12/09

**TYPE OF RULE CHANGE**

**Adopted EMERGENCY Rule Changes**

**Final Proposed Rule Change**

**Proposed Rule Change**

**RULE REFERENCE(S):**

5350            5560            5640            7501

This emergency rule is being implemented as a direct result of Act #1 of the 2009 Special Session, An Act Making Appropriations for the Support of Government. This Act instructed OVHA to make these changes using the emergency rule process because of the fiscal crisis in the state [Act 1, Sec. E.307.1]. OVHA emergency bulletin 09-15E is set to expire on November 12, 2009 and the permanent rule will not complete the APA process in time.

Specifically, Section E.307 of Act #1 states:

“(a) The office of Vermont health access shall limit payment for select drugs used as maintenance treatment to increments of 90-day supplies in Medicaid, the Vermont Health Access Plan, and VermontRx. This limit shall not apply to drugs generally used to treat acute conditions. The drug utilization review board shall make recommendations to the director on the drugs to be selected. This limit shall not apply when the patient initially fills the prescription in order to provide an opportunity for the patient to try the medication and for the prescriber to determine that it is appropriate for the patient’s medical needs.”

**Sidelineing is specific to changes after Bulletin 09-15E.**

*Specific Changes to Rule Sections*

5350	The VHAP requirement for a 90-day supply of maintenance drugs is added.
5560	The VHAP–Pharmacy requirement for a 90-day supply of maintenance drugs is added. Drug Compendium are updated.
5640	The VScript requirement for a 90-day supply of maintenance drugs is added. [aka: Vermont Rx]
7501	The Medicaid requirement for a 90-day supply of maintenance drugs is added.

*Language Changes (to be found throughout the rule changes - these are sidelined):*

<u>Former Language</u>	<u>Current Language</u>
“nursing home”	“nursing facility”
“individual”	“beneficiary”
“recipient”	“beneficiary”
“patient”	“beneficiary”

***Responses to Public Comments of Bulletin 09-17***

A public hearing was held on August 18, 2009 from 9:30 am to 10:30 am and from 1:30 pm to 2:00 pm at the Office of Vermont Health Access, Williston, Vermont. Comments were received at the hearing from Matthew Byrne, Audrey McGregor Reardon, Anthony Otis and Phil O’Neill.

OVHA received written comments from Michael Sirotkin o/b/o the Community of Vermont Elders, PhRMA, AstraZeneca, Lila Richardson of the Office of Health Care Ombudsman, Jill Geiger - Lyndonville Pharmacy, Phil O’Neill, Matthew Byrne from Gravel and Shea, and Madeleine Mongan from the Vermont Medical Society.

Their comments are summarized below along with OVHA’s responses.

**Comment:** Requiring pharmacies to provide a 90-day supply for certain maintenance medications could increase the cost of inventory to small pharmacy businesses.

**Response:** Although there may have been an initial increase in costs to procure inventory following the adoption of Bulletin 09-15E, this should not be a recurring issue because the increased length of time between dispensing medications allows for an extended period before re-stocking.

**Comment:** Commenters were concerned that the emergency rules (bulletins 09-15E and 09-19E) were being enacted too quickly for a smooth transition for the 90-day fills, and that prescribers were not given enough time to update prescriptions or request exemptions.

**Response:** Act 1 of the 2009 Special Session became law on June 2, 2009 by a legislative override of the Governor’s veto. Section A.101 states “Agency and department heads are directed to implement staffing and service levels at the beginning of fiscal year 2010 so as to meet this condition unless otherwise directed by specific language in this act or other acts of the general assembly.” Section E. 307 did not contain language that otherwise directed OVHA to implement later than July 1, 2009. OVHA knew they could not implement the program in less than a month, so implementation was set to begin on July 15, 2009. Prescribers and pharmacies were given notice almost a month (not one week) before the initial effective date of July 15, 2009, then OVHA postponed the implementation to August 1, 2009. In June, prescribers and pharmacies received notice via letters, faxes, and banner pages on their Remittance Advice (RA). Prescribers were given the opportunity to request patient lists before implementation to smoothly transition into the 90-day fill requirements. In addition, notices were sent to beneficiaries in June. It has now been in effect for over 3 months.

- Comment:** Treatment decisions and the determination of medical necessity, including prescription dispensing length, should be the result of discussion between physicians and their patients not left to the discretion of pharmacists or states.
- Response:** All insurance companies, including health insurance programs administered by federal and state governments, have the right to set coverage limits. Both state and federal courts have ruled that the physician is not “the sole arbiter of medical necessity” and there are “reasonable limits on a physician’s discretion in determining what treatments are medically necessary.” Treatment decisions are never left up to pharmacists.
- Comment:** The new budget (E.307) includes a provision requiring that certain maintenance drugs be prescribed for a 90 day period rather than allowing a range of prescription length between 30 and 90 days. The prior regulations provided that most drugs could be prescribed for a period between 30 and 90 days. The regulation also provided that there could be a waiver to this prescription period when the prescriber documented a need for a shorter period due to “extenuating circumstances”. The new regulations now provide that prescriptions for any drug which is to be used continuously “for 30 days or more” may be filled for 90 days. It makes no sense to say that a drug that is to be used for more than 30 days but fewer than 90 days may be prescribed and dispensed in a 90 day increment.
- Response:** We agree and the language regarding maintenance drugs has been revised. The new changes provide greater clarity and reinstates language previously removed. The select maintenance drug fill requirements are separate from all other maintenance drug fills.
- Comment:** We are not aware of any legislative discussion that would support regulatory changes in the process by which exceptions to this 90 day prescription can be made, and the proposed regulations are contrary to legislative intent insofar as they change the exception process.
- Response:** E.307 does not specifically include or exclude the possibility of exceptions to the 90-day fill requirement. In this absence, OVHA has acknowledged that there may be extenuating circumstances for specific beneficiaries, and has, therefore, created the option for prescribers to request exceptions.
- Comment:** There is concern that some individuals are not able to manage their prescriptions because of mental health or cognitive issues. Others should not have large prescription doses because of a history of substance abuse or suicidal ideation. When these situations exist it is obvious that the rationale for allowing a shorter prescription period may apply to all or most prescriptions. There should be some provision for one provider to document the reason and ask for the shorter prescribing period for all relevant prescriptions, and that these exception forms are included in the rule.
- Response:** Since Section E.307 of Act 1 does not specifically include the availability of exceptions to the 90-day maintenance fill for specific drugs, OVHA has acknowledged that there may be extenuating circumstances for specific beneficiaries, and has, therefore, created the option for prescribers to request exceptions. This form allows prescribers to list more than one medication on each exemption request. These forms will not be added to the rule so that OVHA can be responsive to form changes that are requested by prescribers and advocates without being subject to the 8-month APA process.

**Comment:** The new rules require drugs to be prescribed and dispensed on increments of 90-day supplies, and include an exception for initial fills. Because the titration process for new drugs may require more than one fill before a drug and dosage that can be prescribed in 90-day amounts is selected, it is recommended that this exception should not be limited to one fill.

**Response:** This has been taken into consideration; the limit does not apply to changes in dosage, because those are considered new prescriptions. After the first fill that determined/set the therapeutic effectiveness and patient tolerance, prescriptions written for those selected maintenance drugs must be rewritten for a minimum of 90 days for the drug to be covered.

**Comment:** The 90-day supply rule completely disrupts the multi-dose packaging system because it creates two different mechanisms for delivering drugs: drugs in the Medicine On Time<sup>®</sup> cassettes and drugs in big jars. The 90-day rule severely inhibits the ability of doctors and other medical professionals to monitor compliance with drug regime.

**Response:** This is incorrect. Only the select maintenance drugs are required to be filled in 90-day increments; other maintenance drugs can be prescribed and dispensed in increments of between 30 and 90 days. Medicaid rule does not preclude prescribers from extending all maintenance drug fills to 90-days so the Medicine On Time<sup>®</sup> cassettes can still be used.

**Comment:** There is uncertainty about what needs to be done for non-maintenance drugs that are prescribed in less than 30-day periods.

**Response:** There are no changes for “acute” care drugs (non-maintenance drugs). Those prescriptions are prescribed and dispensed exactly as they have been.

**Comment:** There should be better communications with pharmacies regarding who has obtained a PA and who has not, and the only way the pharmacy would know would be to bill and see if the claim was paid. Pharmacies should not be forced to provide services without knowing whether they will be paid.

**Response:** Pharmacies were notified in mid-July that they could request the names of all of their customers that will be affected by these changes. Pharmacies are never forced to provide services without knowing whether or not they will be paid.

**Comment:** Implementing the 90-day fill and pilot program, OVHA is causing irreparable harm to beneficiaries of a specific pharmacy due to a disruption of the provision of benefits.

**Response:** There should be no irreparable harm as there should not have been a disruption in benefits since pharmacies were first notified in mid-June of the changes, and again in mid-July, when implementation was extended to August 1, 2009; pharmacies were informed they could request the names of all of their customers that will be affected by these changes. Since these changes impact beneficiaries statewide and not just those at one pharmacy, there is no basis for stating only the customers of that one pharmacy would be harmed.

**Comment:** Under the OVHA regulation, the disabled must prove not only that it is medically necessary, but they must also prove that there are “extenuating circumstances” to obtain access to pharmacy services. The able bodied need only prove that they are medically necessary to access the same services.

**Response:** This is incorrect. Beneficiaries, either disabled or not, do not have to prove anything to access pharmacy services. Prescribers must submit exception forms to OVHA in order to prescribe the select maintenance drugs in less than 90-day supplies for any and all beneficiaries.

**Comment:** Most beneficiaries have no idea that they can use the prior authorization process to keep their benefits. The notice that OVHA sent to beneficiaries made no mention of the prior authorization process. Without notice, no beneficiary can participate in the prior authorization process the state has developed. Since only physicians can file prior authorizations, there is no mechanism for beneficiaries to request a prior authorization or for the disabled to ensure that their physician actually made the prior authorization request.

**Response:** This is incorrect. Beneficiaries have not lost benefits. The delivery and scope of these benefits has changed. Beneficiaries were sent notice in mid-June clearly stating that “drugs for certain long-term treatment must be given to you in 90-day supplies”. Beneficiaries have never been involved with the prior authorization process. A beneficiary’s disability status has no bearing on whether or not the prescriber follows the prior authorization process (or requests an exemption).

**Comment:** Being put in a position to violate the law, have the patient go without medication, or provide medication at a cost that wouldn’t be reimbursed, none of which works. That’s the position that pharmacists have been put in today.

**Response:** Pharmacy practice is governed by both State and Federal law. None of the programs implemented by the OVHA require nor encourage a pharmacist to break the law. It is unclear why the commenter believes they are being forced to do so.

During the 2009-2010 legislative session, various cost containment initiatives were considered. One change in the effort to contain costs is that each time a drug is dispensed, a dispensing fee is paid to the pharmacy, so certain maintenance drugs will be filled in 90-day supplies. Medicaid policy currently allows for the dispensing of maintenance medications in 90-day supplies but few prescriptions are written in this manner. The result is that more dispensing fees are paid than are medically necessary.

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To get more information about the Administrative Procedures Act and the Rules applicable to state rule making go to the website of the Office of the Vermont Secretary of State at: <http://vermont-archives.org/aparules/index.htm> or call Louise Corliss at 828-2863. [General information, not specific rule content information]

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For information on upcoming hearing before the Legislative Committee on Administrative rules go to the website of the Vermont Legislature at: <http://www.leg.state.vt.us/schedules/schedule2.cfm> or call 828-5760.

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Vertical lines in the left margin indicate significant changes. Dotted lines at the left indicate changes to clarify, rearrange, correct references, etc., without changing content.

11/12/09

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5350

5350 Benefit Delivery Systems5351 BenefitsA. Services Requiring Plan Referral (Continued)

- mental health and chemical dependency services;

NOTE: If a participating managed health care plan has a contract with an institution for mental diseases, services are limited to 30 days per episode and 60 days per calendar year.

- podiatry services;
- prescription drugs and over-the-counter drugs prescribed by a physician for specific disease or medical condition;
- over-the-counter and prescription smoking cessation with a limit of two treatment regimens per beneficiary per calendar year.

"Maintenance drug" means a drug approved by the FDA for continuous use and prescribed to treat a chronic condition for a prolonged period of time of 30 days or longer, and includes insulin, an insulin syringe and an insulin needle. It may not be dispensed unless prescribed by a duly licensed medical professional licensed by the state of Vermont to prescribe within the scope of his or her practice and enrolled in Vermont Medicaid.

Apart from the select drugs used for maintenance treatment described below, all other maintenance drugs must be prescribed and dispensed for not less than 30 days and not more than 90 days. Excluded from this requirement are drugs which the beneficiary takes or uses on an "as needed" basis or generally used to treat acute conditions. If there are extenuating circumstances in an individual case which, in the judgment of the prescriber, dictate a shorter prescribing period for these drugs, the supply may be for less than 30 days as long as the prescriber prepares in sufficient written detail a justification for the shorter period. The extenuating circumstance must be related to the health and/or safety of the beneficiary and not for convenience reasons. It is the responsibility of the pharmacy to maintain in the beneficiary's record the prescriber's justification of extenuating circumstances.

Select drugs used for maintenance treatment must be prescribed and dispensed in increments of 90-day supplies. The drug utilization review board shall make recommendations to the director on the drugs to be selected. This limit shall not apply when the beneficiary initially fills the prescription in order to provide an opportunity for the beneficiary to try the medication and for the prescriber to determine that it is appropriate for the beneficiary's medical needs. If there are extenuating circumstances in an individual case which, in the judgment of the prescriber, dictate a shorter prescribing period, an exception request may be made to the Office of Vermont Health Access.

Up to five refills are permitted if allowed by state or federal law.

11/12/09

Bulletin No.09-25E

5560

5560      Prescribed Drugs

Pharmaceutical items include drugs that are obtained through appropriately licensed pharmacies. Payment for prescribed drugs is limited to:

- Registered Vermont pharmacies, including hospital pharmacies; or
- Pharmacies appropriately licensed in another state; or
- A physician, serving in areas without regular pharmacy services, who has been granted special approval to bill these items direct.

Payment is limited to covered items furnished on written prescription from a duly licensed medical professional licensed by the state of Vermont to prescribe within the scope of his or her practice and enrolled in Vermont Medicaid, or on telephoned prescription from a prescriber as previously described and enrolled in Vermont Medicaid processed in compliance with applicable federal and state statutes and regulations.

"Maintenance drug" means a drug approved by the FDA for continuous use and prescribed to treat a chronic condition for a prolonged period of time of 30 days or longer, and includes insulin, an insulin syringe and an insulin needle.

Apart from the select drugs used for maintenance treatment described below, all other maintenance drugs must be prescribed and dispensed for not less than 30 days and not more than 90 days. Excluded from this requirement are drugs which the beneficiary takes or uses on an "as needed" basis or generally used to treat acute conditions. If there are extenuating circumstances in an individual case which, in the judgment of the prescriber, dictate a shorter prescribing period for these drugs, the supply may be for less than 30 days as long as the prescriber prepares in sufficient written detail a justification for the shorter period. The extenuating circumstance must be related to the health and/or safety of the beneficiary and not for convenience reasons. It is the responsibility of the pharmacy to maintain in the beneficiary's record the prescriber's justification of extenuating circumstances.

Select drugs used for maintenance treatment must be prescribed and dispensed in increments of 90-day supplies. The drug utilization review board shall make recommendations to the director on the drugs to be selected. This limit shall not apply when the beneficiary initially fills the prescription in order to provide an opportunity for the beneficiary to try the medication and for the prescriber to determine that it is appropriate for the beneficiary's medical needs. If there are extenuating circumstances in an individual case which, in the judgment of the prescriber, dictate a shorter prescribing period, an exception request may be made to the Office of Vermont Health Access.

Up to five refills are permitted if allowed by state or federal law.

The pharmacist shall not fill a prescription in a quantity different from that prescribed by the physician if payment is to be made by VHAP-Pharmacy, except in an individual case when the quantity has been changed in consultation with the physician.

11/12/09

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5560

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5560      Prescribed Drugs (Continued)

Payment may be made for any preparation, except those unfavorably evaluated, either included or approved for inclusion in the latest edition of official drug compendia: American Hospital Formulary Service Drug Information; United States Pharmacopeia-Drug Information (or its successor publications); and the DRUGDEX Information System; and the peer-reviewed medical literature. These consist of "legend" drugs for which a prescription is required by State or Federal law.

Physicians and pharmacists are required to conform to Act 127 (18-VSA-Chapter 91), otherwise known as the Generic Drug Bill. In those cases where the Generic Drug Bill permits substitution, only the lowest priced equivalent shall be considered medically necessary. If, in accordance with Act 127, the beneficiary does not wish to accept substitution, VHAP-Pharmacy will not pay for the prescription.

11/12/09

Bulletin No.09-25E

5641

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**5641 Maintenance Drugs**

"Maintenance drug" means a drug approved by the FDA for continuous use and prescribed to treat a chronic condition for a prolonged period of time of 30 days or longer, and includes insulin, an insulin syringe and an insulin needle. It may not be dispensed unless prescribed by a duly licensed medical professional licensed by the state of Vermont to prescribe within the scope of his or her practice and enrolled in Vermont Medicaid.

Apart from the select drugs used for maintenance treatment described below, all other maintenance drugs must be prescribed and dispensed for not less than 30 days and not more than 90 days. If there are extenuating circumstances in an individual case which, in the judgment of the prescriber, dictate a shorter prescribing period for these drugs, the supply may be for less than 30 days as long as the prescriber prepares in sufficient written detail a justification for the shorter period. The extenuating circumstance must be related to the health and/or safety of the beneficiary and not for convenience reasons. It is the responsibility of the pharmacy to maintain in the beneficiary's record the prescriber's justification of extenuating circumstances.

Select drugs used for maintenance treatment must be prescribed and dispensed in 90-day supplies. The drug utilization review board shall make recommendations to the director on the drugs to be selected. This limit shall not apply when the beneficiary initially fills the prescription in order to provide an opportunity for the beneficiary to try the medication and for the prescriber to determine that it is appropriate for the beneficiary's medical needs. If there are extenuating circumstances in an individual case which, in the judgment of the prescriber, dictate a shorter prescribing period, an exception request may be made to the Office of Vermont Health Access.

Up to five refills are permitted if allowed by federal or state pharmacy law.

Physicians and pharmacists are required to conform to Act 127 (18 -VSA- Chapter 91), otherwise known as the Generic Drug Bill. In those cases where the Generic Drug Bill permits substitution, only the lowest-priced equivalent shall be considered medically necessary. If, in accordance with Act 127, the beneficiary does not wish to accept substitution, VScript will not pay for the prescription.

Lists of covered drugs classes are maintained and periodically updated by the Office of Vermont Health Access and available upon request.

For beneficiaries whose VScript group income is greater than 175 percent but no greater than 225 percent of the federal poverty level coverage is limited to drugs dispensed by participating pharmacies from manufacturers that as a condition of participation in the program, have signed a rebate agreement with the Office of Vermont Health Access.

11/12/09

Bulletin No.09-25E

7501

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**7501 Pharmaceuticals, Medical Supplies and Equipment - General Information**

Pharmaceutical items include drugs that can only be dispensed with a prescription, over-the-counter drugs, vitamins and related items which are normally obtained through appropriately licensed pharmacies. Medical supplies and equipment include prosthetic devices, durable and non-durable equipment for care of the ill or injured, medical supplies and similar items which may be obtained from a pharmacy, hospital-surgical supply service or home health agency.

Payment for covered items, other than prescribed drugs, is limited to the following providers:

- A Vermont provider approved for participation in Medicare; or
- An out-of-state provider, approved either for Medicare participation or for Medical Assistance (Title XIX) participation by the single state agency administering the Title XIX Program within the state where it is located.

Payment for prescribed drugs is limited to Vermont Medicaid enrolled providers who are:

- Registered Vermont pharmacies, including hospital pharmacies; or
- Pharmacies appropriately licensed in another state; or
- A physician, serving an area without regular pharmacy services, who has been granted special approval to bill these items direct.

Payment is limited to covered items furnished on written prescription of a duly licensed medical professional licensed by the state of Vermont to prescribe within the scope of his or her practice and enrolled in Vermont Medicaid, or on telephoned prescription from a prescriber as previously described and enrolled in Vermont Medicaid processed in compliance with applicable federal and state statutes and regulations.

"Maintenance drug" means a drug approved by the FDA for continuous use and prescribed to treat a chronic condition for a prolonged period of time of 30 days or longer, and includes insulin, an insulin syringe and an insulin needle.

Apart from the select drugs used for maintenance treatment described below, all other maintenance drugs must be prescribed and dispensed for not less than 30 days and not more than 90 days. Excluded from this requirement are drugs which the beneficiary takes or uses on an "as needed" basis or generally used to treat acute conditions. If there are extenuating circumstances in an individual case which, in the judgment of the prescriber, dictate a shorter prescribing period for these drugs, the supply may be for less than 30 days as long as the prescriber prepares in sufficient written detail a justification for the shorter period. The extenuating circumstance must be related to the health and/or safety of the beneficiary and not for convenience reasons. It is the responsibility of the pharmacy to maintain in the beneficiary's record the prescriber's justification of extenuating circumstances.

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Bulletin No.09-25E

7501

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7501 Drugs and Pharmaceutical Items, Medical Supplies and Equipment (Continued)

Select drugs used for maintenance treatment must be prescribed and dispensed in increments of 90-day supplies. The drug utilization review board shall make recommendations to the director on the drugs to be selected. This limit shall not apply when the beneficiary initially fills the prescription in order to provide an opportunity for the beneficiary to try the medication and for the prescriber to determine that it is appropriate for the beneficiary's medical needs. If there are extenuating circumstances in an individual case which, in the judgment of the prescriber, dictate a shorter prescribing period, an exception request may be made to the Office of Vermont Health Access.

Up to five refills are permitted if allowed by federal or state pharmacy law.

For recipients in a NF or ICF/MR see 7501.6.

The pharmacist shall not fill a prescription in a quantity different from that prescribed by the physician if payment is to be made by Medicaid except in an individual case when the quantity has been changed in consultation with the physician.

When the same drug in the same strength is prescribed for more than one member of a family at one time, the pharmacist must submit one prescription for each family member for payment purposes.

Claims for vendor payment are submitted to and processed by the fiscal agent only; there is no provision for direct reimbursement to recipients or to nursing facilities for payments they may make to a pharmacy or supplier.