PHARMACY SERVICES PROVIDER MANUAL

OCTOBER 1, 2023

South Carolina Department of Health and Human Services

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PROGRAM OVERVIEW

PROGRAM DESCRIPTION

Pharmacy Practice Requirements

The State of South Carolina (South Carolina or State) Department of Health and Human Services (SCDHHS) requires that providers of Pharmacy Services to South Carolina Medicaid beneficiaries adhere to all state and federal requirements regarding the practice of pharmacy. Additionally, South Carolina Medicaid-enrolled pharmacies located outside of South Carolina must adhere to all federal and state requirements specific to the state in which the pharmacy is located.

Pharmacy

"Pharmacy" means a location for which a pharmacy permit is required from its respective Board of Pharmacy and in which prescription drugs and devices are maintained, compounded and dispensed for patients by a pharmacist. This definition includes a location where a pharmacist provides pharmacy-related services. All such pharmacies are eligible to apply for participation in the South Carolina Medicaid program. (See the Provider Administrative and Billing Manual regarding enrollment procedures.) South Carolina Board of Pharmacy-permitted non-dispensing drug outlets are **ineligible** for Medicaid participation.

Out-of-State pharmacies *must* be enrolled with the South Carolina Medicaid program in order to be reimbursed for any prescriptions dispensed to South Carolina Medicaid beneficiaries. Non-resident pharmacies (i.e., pharmacies located outside of South Carolina) whose primary business is filling mail-order prescriptions must have a special permit issued by the South Carolina Board of Pharmacy in order to engage in the sale, distribution, or dispensing of legend drugs or devices in South Carolina. This special non-resident South Carolina permit is required in order to be eligible for Medicaid participation.

Providers desiring to enroll in the South Carolina Medicaid program must have a licensed pharmacist on the premises and may not subcontract pharmaceutical services that are to be billed to the Medicaid program.

Scope of Coverage

The basic objective of the Medicaid Pharmacy Services Program is to provide needed pharmaceuticals for the purpose of saving lives in an emergency or a short-term illness, for sustaining life in chronic or long-term illness, or for limiting the need for hospitalization. This manual outlines additional requirements and restrictions set forth by SCDHHS in its standards for providing services to Medicaid beneficiaries.

Pharmacy Services include the dispensing of most *generic* legend (i.e., products that require a prescription in order to be dispensed) and most *generic* non-legend pharmaceuticals to eligible beneficiaries.

Only **rebated** pharmaceuticals that are Food and Drug Administration (FDA) approved may be considered for reimbursement.

For each pharmaceutical dispensed, a valid prescription authorized by a licensed practitioner (physician, dentist, optometrist, podiatrist, or other health care provider authorized by law to diagnose and prescribe drugs and devices) must be on file.

The South Carolina Medicaid pharmacy benefit will not cover drug samples, pharmaceuticals obtained through patient assistance programs, or any other free pharmaceuticals. Additionally, Medicaid will not provide any payments for items or services provided under the State Plan or under a waiver to any financial institution or entity located outside of the United States.

Non-Formulary Program
The SCDHHS maintains an "open", or non-formulary, Pharmacy Services Program. With certain specified exceptions, most rebated *generic* legend and *generic* non-legend pharmaceuticals are routinely covered by the Medicaid program. However, some drugs require clinical prior authorization (PA) in order to be considered for reimbursement by Medicaid. The National Drug Code (NDC) number listed on the product's stock container or packaging is used for identification and claims filing.

Pharmacy Point-of-Sale (POS) System
The South Carolina Medicaid program has contracted with Magellan Medicaid Administration, Inc. (Magellan) to process prescription drug claims using a computerized POS system. This system gives participating pharmacies online, "real time" access to beneficiary eligibility, drug coverage (to include PA requirements), prescription limitations, pricing and payment information, and prospective drug utilization review (ProDUR). Although not mandatory, providers are strongly encouraged to utilize POS transmission in order to avoid potentially costly rejections of submitted claims. Magellan only accepts claims from participating pharmacies which have valid provider contracts and who are enrolled with the South Carolina Medicaid Pharmacy Services Program. For more information on POS claims submission and to request billing specifications, pharmacy providers should contact Magellan's Provider Relations Department at: +1 804 965 7619. (Additional claims submission options and requirements are discussed in detail in the Magellan Pharmacy Provider Manual which can be accessed here: http://southcarolina.fhsc.com.)

Omnibus Budget Reconciliation Act of 1990 — Rebate Requirements
The Omnibus Budget Reconciliation Act of 1990 (OBRA) requires that pharmaceutical manufacturers have a rebate agreement in effect with the Centers for Medicare and Medicaid Services (CMS) in order for their pharmaceuticals to be reimbursed by the Medicaid program.

The pharmaceuticals of those manufacturers who have **not** entered into such an agreement are non-covered by the Medicaid program. However, *devices or supplies* such as insulin syringes and over-the-counter (OTC) family planning products remain as covered items since this limitation in coverage applies only to *medications* dispensed to Medicaid beneficiaries.

South Carolina Medicaid requires the submission of a product's 11-digit NDC number. The first five digits of the NDC number comprise the labeler code; it is this labeler code that identifies the manufacturer of the product. The Medicaid pharmacy claims processing system uses this labeler code to determine if the pharmaceutical is rebated and therefore, potentially, Medicaid-covered. It should be noted that manufacturers that utilize several different labeler codes may *not* have rebate agreements in effect with CMS for *all* of their labeler codes. Therefore, the labeler code is the controlling factor rather than the manufacturer's name.

Manufacturer rebate payments to the State are based on prescription claims payment data identified by NDC number. To assure that the appropriate manufacturer is invoiced for the rebate monies due the State, pharmacy providers are required to submit accurate NDC numbers when filing Medicaid claims to Magellan, the POS contractor for South Carolina Medicaid.

The NDC number being submitted to Medicaid for reimbursement must be the actual NDC number on the package or container from which the medication was dispensed.

Submitting inaccurate NDC numbers may result in: SCDHHS' billing the wrong manufacturer for the rebate, disputes in the amount of rebate due, and post payment review of the records of the pharmacy provider.

Additionally, failure to correctly reflect the actual NDC number dispensed may negatively impact revenues generated for the State and potentially result in a greater expenditure of State funds. Therefore, it is imperative that pharmacists take care to correctly identify the specific NDC number of the pharmaceutical dispensed. Appropriate updates to computer software programs will facilitate the use of accurate NDC numbers.

Note: References to supporting documents and information are included throughout the manual. This information is found at the following locations:

- [Provider Administrative and Billing Manual](#)

- [Forms](#)

- [Section 4 - Procedure Codes](#)

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COVERED POPULATIONS

ELIGIBILITY/SPECIAL POPULATIONS

Long-Term Care Beneficiaries

Regarding *non-dually eligible* long-term care patients (including swing bed patients), providers are advised that, with the exception of insulin, *all* OTC products must be furnished by the nursing facility (NF), and as such, these items may not be billed separately to the Pharmacy Services Program. OTC drugs are reimbursed in the per diem rate for all facilities in accordance with procedures established by SCDHHS. Therefore, OTC products may not be billed to the patient/responsible party, relative, organization or any other entity.

Nearly all parenteral therapies furnished to non-dually eligible long-term care patients are routinely covered and do not require PA in order to be billed to Medicaid.

Deductions for Non-Covered Medical Expenses

Non-dually eligible individuals in NFs, whose cost of care is sponsored by Medicaid and who have monthly recurring income, are allowed deductions from their monthly income if they incur medical expenses which are not covered by Medicaid or another third-party.

Non-covered medical expenses are those expenses which are recognized by State law as medical expenses, but which are not covered by Medicaid or any other third-party payer such as Medicare, TRICARE, private insurance, etc. Non-covered medical services include those items/services that exceed Medicaid limits, (excluded, less than effective or non-rebated drugs). Non-covered services do not include items/services that are recognized in allowable costs for Medicaid long-term care rate setting purposes.

A deduction will be allowed when the following information is provided to the NF:

• A bill which states the item/service furnished, the date rendered and the cost.

• A statement or prescription from a licensed practitioner that verifies medical necessity.

The deduction(s) will be made in the month in which the required documentation is provided to the NF. Deductions will not be allowed for expenses that were incurred prior to entering the NF. Services/items, which were rendered more than three months prior to the month of the request, will not be allowed as deductions except under the following circumstances:

• When eligibility is determined for a retroactive period, or

• When there is a delay in approving an application on an individual who is a resident of a NF, or

- When there is a delay in a determination by a third-party payer regarding coverage of an item/service.

Deductions will be allowed for prescription drugs that are noted as general exclusions that are not covered by another third-party payer. The amount deducted cannot exceed the lesser of $12.00 or the actual cost of the prescription.

Eligibility

The Medicaid program reimburses for covered medical services for individuals who have a valid 10-digit identification number (as printed on the permanent plastic South Carolina Healthy Connections Card) and whose eligibility for that date of service has been verified. For pharmacy providers, eligibility verification may be accomplished by claims submission through Magellan's POS system.

It is important to note that *possession of the plastic Medicaid card does not guarantee Medicaid eligibility*; beneficiaries may become ineligible for Medicaid for a given month only to regain eligibility at a later date. Therefore, it is possible that a beneficiary will present a Medicaid card during a period of ineligibility. To avoid such rejections, pharmacy providers are strongly encouraged to submit claims via Magellan's "real time" POS system. Pharmacists are not obligated to dispense medications if the beneficiary (or his/her caregiver) is unable to present the plastic Medicaid card or other appropriate documentation containing the individual's Medicaid health insurance number. (Refer to the Provider Administrative and Billing Manual for further information on Medicaid eligibility and for a detailed description of the South Carolina Healthy Connections Medicaid Insurance Card.)

The POS system also facilitates claims processing by identifying those Medicaid beneficiaries enrolled in certain waiver programs who may be eligible for enhanced benefits; conversely, it also alerts the pharmacy provider that, in some instances, Medicaid coverage may be restricted or limited.

Use of the POS system provides immediate verification that the individual is currently eligible for Medicaid coverage and also determines if benefits are restricted or enhanced.

Therefore, if non-POS claims are submitted, the provider is at-risk for possible non-payment by Medicaid due to beneficiary ineligibility or other factors.

In order to ensure that Magellan and SCDHHS Pharmacy Services staff resources are appropriately utilized, providers should instruct beneficiaries to call the Magellan Beneficiary Call Center at: +1 800 834 2680 (toll-free) for inquiries regarding Pharmacy Services-related issues. Other Medicaid inquiries from beneficiaries should be directed to: +1 888 549 0820 (toll-free).

In addition to providing traditional fee-for-service (FFS) medical care coverage, SCDHHS has implemented the South Carolina Medicaid Managed Care Program. Providers should refer to the Managed Care Supplement for additional information.

Note: The above requirements are specific to FFS Medicaid. Many beneficiaries are now enrolled in a Medicaid Managed Care program and, as such, are subject to the guidelines as outlined in their specific managed care plan. Providers must verify plan participation prior to rendering services. Providers should refer to the Managed Care Supplement for additional information.

Special Groups/Issues

Medicare Part D Prescription Drug Coverage

On January 1, 2006, CMS implemented Medicare prescription drug coverage, known as Medicare Part D. Under Part D, CMS contracts with Prescription Drug Plans (PDPs) to make available a drug coverage benefit for Medicare eligibles (*i.e.,* individuals who have Medicare Parts A or B).

Although individuals eligible for both Medicare and Medicaid (*i.e.,* dual eligibles) no longer receive the complete drug coverage benefit through Medicaid, dual eligibles continue to be eligible for all other Medicaid services that are currently provided. Furthermore, Medicaid continues to cover certain specified PDP-excluded drug categories for dual eligibles only.

Resources for Medicare Part D Beneficiaries

Beneficiaries may apply or obtain Medicare Part D and PDP information by:

Telephone: +1 800 MEDICARE (+1 800 633 4227)
Website: http://www.medicare.gov/
Online application: http://www.socialsecurity.gov/prescriptionhelp/

Auto-Enrollment of Dual Eligibles

To participate in Part D, Medicare eligibles must have enrolled in a PDP that CMS has approved for South Carolina. To ensure that dual eligibles continue to have prescription drug coverage, CMS automatically enrolls (auto-enrolls) dual eligibles into PDPs if they have not self-enrolled. It should be noted that the PDP into which CMS has auto-enrolled a beneficiary may not be the plan that best accommodates the individual's needs (due to formulary restrictions, pharmacy provider network issues, etc.).

South Carolina PDPs

There are many different companies that have an assortment of prescription plans available for South Carolina Medicare beneficiaries. Enrollment in a PDP is generally for the calendar year. Medicare beneficiaries may only switch plans during the annual open enrollment period. However, dual eligibles may change plans at any time by calling: +1 800 MEDICARE and enrolling in their plan of choice.

Note: Medicare-eligibles who are residents of South Carolina must enroll in a PDP that CMS has approved for Part D beneficiaries in South Carolina.

Medicaid Point-of-Sale (POS) Denial Responses

Pharmacy claims submitted via POS to South Carolina Medicaid for a dual eligible will deny with National Council for Prescription Drug Programs (NCPDP) response code 41, "submit bill to other

processor or primary payer". Pharmacy providers should do an E1 query through Medicare to determine which PDP a beneficiary is enrolled in.

Medicare Part B Drugs

Providers should note that Part D is an additional Medicare benefit and does not replace Medicare Part A, B or C. Medicare Part B coverage remains viable for certain designated drugs under specific conditions (e.g., immunosuppressants following a Medicare-sponsored organ transplant, oral chemotherapy agents, oral anti-emetics, etc.). Therefore, for dually eligible beneficiaries, pharmacists will continue to submit such claims (using their respective *supplier* billing numbers) to Medicare Part B for payment consideration. In some circumstances, however, these drugs may be deemed non-covered by Medicare Part B. An example would be an oral chemotherapy drug such as methotrexate when used to treat rheumatoid arthritis. Useful information regarding those drugs that are covered by Part B (rather than Part D) may be found by clicking on Parts B and D information at http://www.cms.hhs.gov/pharmacy. Pharmacy Services providers should refer to the Medicare Parts B and D Coverage Issues Table at this website link, to be aware of those circumstances when these drugs may be deemed non-covered by Medicare Part B and, therefore, billable to Part D.

If Medicare Part B denies payment because the drug is considered non-covered for the diagnosis indicated, the claim should then be submitted to the beneficiary's Medicare Part D PDP. To facilitate claims submission, it may be necessary for the pharmacist to contact the prescriber for additional diagnostic or patient-specific information in order to determine which payer (Part B or Part D) should be billed as primary.

If Medicare Part B reimburses for any portion of the Pharmacy Services provider's submitted charge (or if the claim paid amount was applied to the Medicare Part B annual deductible), the pharmacist should bill Medicaid secondarily using the Magellan Services POS system.

Note: Medicaid cannot be billed secondarily for Medicare Part B-covered vaccines. In those instances, the beneficiary's Medicare Part D PDP must be billed for any allowable secondary payment.

If the amount paid was applied toward the annual deductible, a copy of the Medicare Part B Explanation of Benefits (EOB) must be faxed to the Magellan Services Clinical Call Center at: +1 888 603 7696 (toll free). Pharmacists are encouraged to indicate the beneficiary's 10-digit Medicaid identification number on Medicare EOBs furnished to Magellan Services. While subsequent fills for that specific drug therapy will continue to require PA, faxing additional copies of the Medicare EOB will not be necessary each time the prescription is refilled.

When billing a prior authorized claim secondarily to Medicaid, the coordination of benefits (COB) data elements are applicable and must be appropriately populated.

Medicaid and PDP — Non-Covered Drugs

Providers are aware that prescription plans have different formularies, preferred drug lists (PDLs), and PA programs; the PDPs have these types of processes and programs in effect. It is important for beneficiaries to know that the PDP must notify the individual 60 days before removing one of his or her prescriptions from PDP coverage. Regarding PDP non-covered drugs, providers should be aware that *South Carolina Medicaid will **not** be a secondary payer for products such as a PDP's non-formulary drug or non-preferred drug or a PDP's PA-required drug.*

Medicaid and Certain PDP — Excluded Drug Categories

There are several drug categories that PDPs are not required by CMS to cover. *If* the PDP has chosen not to cover such items, South Carolina Medicaid will provide coverage of those products ***for dual eligibles only***, subject to Medicaid's existing rules and policies (i.e., product must be rebated; product may require PA under Medicaid rules, etc.). The PDP-excluded drug categories include: cough and cold products, vitamins and/or minerals, and OTC drugs (except for a pharmaceutical such as an OTC proton pump inhibitor [PPI] or an OTC non-sedating antihistamine since those drugs belong specifically to PDP-covered therapeutic classes). PDPs cover barbiturates used in the treatment of epilepsy, cancer or a chronic mental health disorder, and benzodiazepines for dual eligibles.

Only vitamins, minerals and OTC drugs may be billed to South Carolina Medicaid after the pharmacy provider receives a denial from the **dual eligible's** PDP.

Long-Term Care Facilities

Providers should note that full-benefit dual eligibles residing in long-term care facilities such as nursing homes are not responsible for any cost-sharing (e.g., copayments) under the Part D benefit. These individuals retain their limited personal needs allowances for their personal expenses and do not have to spend the allowance on drug costs. Additionally, providing OTC drugs remains the responsibility of the long-term care facility; therefore, OTC coverage for long-term care residents is not the responsibility of the PDP or the Medicaid outpatient drug program.

Regarding nursing homes and the Part D benefit, PDPs are required to provide convenient access to long-term care pharmacies serving Part D enrollees residing in long-term care facilities. Nursing home staff members are encouraged to use the web-based Prescription Plan Finder tool at: http://www.medicare.gov/ for individual resident inquiries.

CMS's Contingency Plan for Dual Eligibles

If a situation occurs where a dual eligible needs to have prescriptions filled at the pharmacy and this individual is unaware of the PDP into which he or she is enrolled, the pharmacy provider should conduct an E1 query to determine what drug plan the beneficiary is covered under and what the copayment level should be.

If the dual eligible is not enrolled in a PDP, then the pharmacy provider should follow through with CMS's POS-facilitated enrollment process **to ensure that the individual obtains his or her needed prescription medication(s) before leaving the pharmacy**. Pharmacy providers should note that this process is applicable to only **dual eligibles**.

CMS has contracted with Humana to serve as the enrollment contractor for non-enrolled dual eligibles. Humana will expedite the validation of dual eligibility and process claims at POS to facilitate enrollment in a Medicare Part D Plan with low-income premium subsidy for dual eligibles that were not auto enrolled. This enrollment in Contract X0001 will be done through the Limited Income Newly Eligible Transition (LINET) program.

Pharmacy providers may execute an E1 query to determine whether a dual eligible is already enrolled in Contract X0001. Beneficiaries may receive services through Contract X0001 for up to two months until CMS enrolls them into another plan. The pharmacy provider should submit an E1 query each new month to determine when the beneficiary has been enrolled into a permanent Part D plan. Pharmacy providers and dual eligible beneficiaries may contact Humana at: +1 800 783 1307 for assistance with LINET.

Family Planning Program

Family planning services are defined as preconception services that prevent or delay pregnancies and do not include abortion or abortion-related services.

The Family Planning Program is a limited-benefit program that provides coverage for preventive health care, family planning services and family planning-related services. Family Planning is available to men and women of all ages in South Carolina whose annual family income does not exceed 194% of the Federal Poverty Level and who are ineligible for full Medicaid coverage under any other eligibility category. Services covered under the Family Planning eligibility category will continue to be covered under Family Planning.

Outpatient contraceptive pharmaceuticals and devices (both legend and OTC), family planning office or clinic examinations, related laboratory services, counseling services related to family planning, and birth control methods are covered under this program.

Additionally, testing and treatment for certain sexually transmitted infections (STIs) found during the family planning visit will be covered. Beneficiaries can receive antibiotic treatment for the following STIs: syphilis, chlamydia, gonorrhea, herpes, candidiasis and trichomoniasis. **The physician must write the International Classification of Diseases, 10th Revision (ICD-10) diagnosis code on the prescription for the STI treatment in order for the medication to be considered for reimbursement by Medicaid.**

Providers are reminded that Medicaid beneficiaries must present a prescription for *any* pharmaceuticals or devices dispensed to them, including OTC items.

All prescriptions written for STIs, family planning pharmaceuticals, devices or supplies are exempt from the collection of the $3.40 Medicaid copayment.

Participants in the Family Planning Program receive a Healthy Connections Checkup card; thus, Pharmacy Services providers who do not utilize the Medicaid POS system for claims submission will be at-risk for possible claims rejection.

Tuberculosis (TB) Program

SCDHHS offers a limited coverage benefit to persons with latent TB or active TB infection/disease who are uninsured or underinsured who do not meet the eligibility criteria for full Medicaid benefits. Beneficiaries approved for this program will also receive Family Planning Services. A copay of $3.40 will be required for TB drugs, and all PDL rules will be applied.

In addition, coverage of TB drugs will be carved out of the Managed Care benefit and will be provided through the South Carolina Department of Health and Environmental Control (SCDHEC).

Medicaid Hospice Services

SCDHHS offers a limited coverage benefit to persons deemed hospice eligible. The Hospice provider will make pharmacies aware of covered hospice medications, and the pharmacy provider is responsible for billing these medications directly to the hospice provider. All other eligible medications may be covered under the pharmacy benefit.

Palmetto SeniorCare Capitated Billing Program

Palmetto SeniorCare is a Program of All-Inclusive Care for the Elderly (PACE) program that provides an array of services to Medicaid beneficiaries eligible for long-term care who reside in Anderson, Bamberg, Calhoun, Greenville, Lexington, Orangeburg, Pickens, or Richland, counties who are age 55 or older. These beneficiaries have voluntarily agreed to receive medical care *only* through PACE. Thus, they waive the right to choose any providers other than those providers who receive prior approval from PACE. Instead, these individuals accept the PACE as sole provider of all direct or indirect medical care.

A capitated payment is made to PACE each month for each enrolled beneficiary. **Once an individual is enrolled in the PACE Program, neither Medicaid nor Medicare will pay any other providers for services rendered.** Pharmacy Services providers who do not utilize Magellan's POS system for claims submission will be at risk for possible claims rejection. Questions regarding the PACE Program may be directed to the PSC at +1 888 289 0709 or you may submit an online inquiry at: http://www.scdhhs.gov/contact-us.

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ELIGIBLE PROVIDERS

PROVIDER QUALIFICATIONS

Pharmacist

A "pharmacist" is an individual health care provider licensed by the State to engage in the practice of pharmacy.

A pharmacist is a learned professional authorized to provide patient care services within the scope of their knowledge and skills.

"Practice of Pharmacy" means:

- The interpretation, evaluation and dispensing of prescription drug orders in the patient's best interest.

- Participation in drug and device selection, drug administration, prospective drug reviews, and drug or drug-related research.

- Provision of patient counseling and the provision of those acts or services necessary to provide pharmacy care and drug therapy management; and responsibility for compounding and labeling of drugs and devices (except labeling by a manufacturer, re-packager, or distributor of non-prescription drugs and commercially packaged legend drugs and devices).

- Proper and safe storage of drugs and devices and maintenance of proper records for them; or the offering or performing of those acts, services, operations or transactions necessary in the conduct, operation, education, management and control of pharmacy.

- South Carolina Licensed Pharmacists are allowed to provide evaluation and management services for new and established patients when delivering contraceptives or performing urine pregnancy tests. Pharmacists must be enrolled as an individual provider with Healthy Connections Medicaid and provide information on the Medicaid enrolled pharmacy or pharmacies where they will be providing this service. Refer to the Physician's Manual for billing guidance.

Patient Counseling

Patient counseling is defined as the oral or written communication by the pharmacist to a patient or caregiver providing information on the proper use of drugs and devices.

South Carolina Medicaid requires that, upon receipt of a prescription drug order for a "new" medication and following review of the patient's pharmacy record, the pharmacist shall personally offer counseling to the patient or the patient's agent. Using his or her best professional judgment, the pharmacist's counseling shall include a discussion of those matters that the pharmacist considers

appropriate for the patient or patient's agent in that particular situation. The discussion must be in person, whenever practicable, or by telephone or written communication and shall include appropriate elements of patient counseling.

Information Requests

All pharmacy enrolled providers are required to complete any information requests, including surveys, from the agency or on behalf of the agency. All requests must be completed by the requested due date.

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COVERED SERVICES AND DEFINITIONS

MEDICAID COVERAGE OF TOBACCO CESSATION PRODUCTS

Full coverage FFS Medicaid beneficiaries have access to a comprehensive tobacco cessation benefit, including FDA-approved medications that meet federal rebate requirements (brand or generic).

Tobacco cessation products are exempt from PA and copayment requirements. There is no limit to the number of quit attempts allowed in a calendar year. Medically appropriate combination therapies are also covered.

General edits on days' supply are based on product dosing in manufacturer package inserts. Prescribers are encouraged to reference the American Academy of Family Physicians Pharmacologic Product Guide for FDA-approved medications for smoking cessation for more information on product guidelines.

As with all other outpatient medications, a prescription must be presented at the pharmacy before the medication can be dispensed. This applies to OTC products as well as legend (non-OTC).

Dual-eligible members can receive OTC products through Medicaid, but the individual's Medicare Part D PDP must cover prescriptions for legend tobacco cessation products.

For further questions about this benefit, prescribers should contact the Magellan's Clinical Call Center at: +1 866 247 1181.

Zidovudine (AZT) Syrup for Newborns

In an effort to ensure timely access to critical AZT therapy for at-risk newborns and to maximize patient compliance, the SCDHHS will allow the pharmacy provider to bill Medicaid using the mother's Medicaid health insurance number when dispensing the initial six weeks' supply of AZT syrup. Billing this drug to the mother's Medicaid identification number is permissible *only* in those instances where the newborn has not yet been assigned a Medicaid health insurance number at the time of dispensing. This special billing policy pertains *only* to the initial dispensing of AZT syrup; **other medications dispensed to newborns may not be billed to Medicaid in such a manner.**

Medicaid Coverage of OTC Pharmaceuticals

SCDHHS reimburses for most *rebated* OTC generic pharmaceuticals, including those products formerly designated as "legend".

The majority of nationally marketed OTC products are rebated by their respective manufacturers and may be considered for Medicaid reimbursement within program guidelines. Most chain pharmacies do not provide federally mandated rebate monies for their "house brand" OTCs; and thus, those specific

products are deemed not covered. Additionally, in some instances, PA may be required (e.g., product not on PDL).

For each OTC product dispensed, a valid prescription authorized by a licensed practitioner (i.e., physician, dentist, optometrist, podiatrist, or other health care provider authorized by law to diagnose and prescribe drugs and devices) must be on file. Insulin and insulin syringes are reimbursed through the Pharmacy Services Program. Diabetic devices and supplies (e.g., glucometers, test strips, and lancets, etc.) are covered under the South Carolina Medicaid Durable Medical Equipment (DME) program; however, certain preferred test strips, lancets and spacers for metered dose inhalers may be billed under the Pharmacy POS system.

Coverage Policy for Multi-Ingredient Compounds

Providers should be aware that multi-ingredient compounds are *non-covered* by South Carolina Medicaid if that specific combination of ingredients is commercially available from a pharmaceutical manufacturer. Therefore, such compounds must not be billed to Medicaid. Additionally, the reconstitution of commercially available products is not considered compounding and as such, may not be billed to Medicaid as a compound. (See the Magellan Medicaid Provider Manual – Pharmacy Point of Sale, in addition to a Magellan educational tool titled Multi-Ingredient Compound Billing Reference Guide.)

Continuous Glucose Monitors

Certain Continuous Glucose Monitors (CGMs) and insulin pumps are covered under the pharmacy benefit. Refer to the Magellan Medicaid website to view the DME Diabetic Supply Listing for the preferred product listing covered under the Pharmacy Benefit. .All CGMs and insulin pumps under the pharmacy benefit will require PA. The physician may request PA by calling Magellan at: +1 866 247 1181.

Hemophilia Factor

Effective with dates of service on or after March 1, 2023, Hemophilia factor will be covered and billed under the pharmacy benefit.

For beneficiaries enrolled in a Medicaid Managed Care Organization (MCO), the MCO is responsible for the provision and reimbursement of hemophilia factor.

Immunizations

The following Immunization agents are covered under the pharmacy benefit: influenza, pneumococcal, rabies, Tdap, tetanus and diphtheria toxoids (Td), hepatitis vaccines, and HPV.

NON-COVERED SERVICES AND DEFINITIONS

The following is a listing of products *excluded* from South Carolina Medicaid coverage. These items are considered non-covered, regardless of circumstance:

1. Weight control products (except for lipase inhibitors).

2. Investigational pharmaceuticals or products.

3. Pharmaceuticals determined by the FDA to be less than effective and identical, related or similar drugs (frequently referred to as "Drug Efficacy Study Implementation [DESI]" drugs).

4. **Most injectable pharmaceuticals administered by the practitioner in the office, in an outpatient clinic or infusion center, or in a mental health center are not covered.**

    Note: Medicaid reimbursement for Cerezyme® (imiglucerase) or Respigam® is limited solely to physician providers, hospital providers, and infusion centers through their respective Medicaid program area (e.g., physicians services, hospital services, etc.). Certain physician injectable products may be billed via POS by the Pharmacy Services provider if administered in a physician's office or clinic or in a South Carolina Department of Mental Health clinic. Due to safety and product stability issues, the pharmacy provider must deliver these pharmaceuticals **directly** to the physician's office or clinic. (See *Claims Submission for Certain Physician — Injectable Products* within this manual for additional information.)

5. Products used as flushes to maintain patency of indwelling peripheral or central venipuncture devices. These products are not covered under Pharmacy Services but are covered through DME.

6. Fertility products.

7. Pharmaceuticals that are not rebated.

8. Nutritional supplements (Enteral nutrition therapy administered through a feeding tube and Total Parenteral Nutritional [TPN] therapy may be covered through DME; however, neither program reimburses for oral nutritional supplements.)

9. Oral hydration therapies for adults.

10. Pharmaceuticals used for cosmetic purposes or hair growth.

11. Cough/Cold medications.

12. Devices and Supplies (e.g., diabetic supplies, infusion supplies, etc.). These items may be billed through DME. However, certain glucometers, test strips, lancets, spacers for metered dose inhalers, and certain (stand-alone) CGMs may also be billed through the Pharmacy POS system by an enrolled DME provider using their enrolled pharmacy National Provider Identifier (NPI).

13. Products used to treat sexual or erectile dysfunction.

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UTILIZATION MANAGEMENT

PRIOR AUTHORIZATION

Program Requirements — Prior Authorization

Pharmaceuticals requiring PA are outlined below. South Carolina Medicaid's PA program, administered by Magellan, is comprised of a clinical PA process as well as a non-clinical PA process. Regarding *clinical* PA requests, the *prescriber* or the prescriber's designated office personnel must contact Magellan's Clinical Call Center (+1 866 247 1181 [toll-free]) in order to furnish necessary patient-specific medical information. (Although faxed requests from prescribers are permissible, *telephoned PA requests may be processed more expeditiously* since all needed information can be supplied at the time of the telephone call.) Magellan employs a clinical staff of pharmacists and pharmacy technicians whose primary responsibilities include responding to prescribers' PA requests. Based on established criteria that is proprietary and confidential, and in accordance with current medical practices, Magellan makes the determination regarding coverage of the product prescribed for the beneficiary. The clinician reviewing the request may refer it to the Medical Director for further review if needed. The Magellan Clinical Call Center telephone number is reserved for use by health care professionals and should not be furnished directly to beneficiaries. Magellan's *beneficiary call center* telephone number for questions regarding Pharmacy Services-related issues is: +1 800 834 2680; providers may furnish the beneficiary call center telephone number to Medicaid beneficiaries *for Pharmacy Services-related issues only.*

Upon verification that usage is appropriate and in compliance with Medicaid policies, *non-clinical PAs generally may be processed at the POS by the pharmacist* by utilizing specific claims filing instructions contained in the Magellan Pharmacy Provider Manual. (If additional assistance is needed regarding non-clinical PAs, the provider may contact Magellan's Technical Call Center at: +1 866 254 1669 [toll-free].)

It should be noted that for certain categories of drugs, the need for PA is based on the age and/or gender of the beneficiary or on the quantity to be dispensed.

Maximum quantity limitations have been established for certain drugs; these established maximum quantities are based upon a 31-days' supply of medication and have been determined using the drug manufacturers' current dosing recommendations. SCDHHS operates a Dose Optimization program, an enhancement to the current Quantity Limits program. Listings of drugs subject to quantity limitations may be found at: http://southcarolina.fhsc.com. See *Quantity of Medication* within this manual for detailed information. Furthermore, only *rebated* pharmaceuticals may be considered for possible reimbursement through the PA process.

Note: With few specified exceptions, Medicaid does not routinely cover brand name products for which there are therapeutically equivalent generic products available. See *Medicaid Coverage of Generic Products* within this manual for further information.

The drugs (or categories of drugs) outlined below require PA. Those products requiring *clinical* PA by the prescriber are designated as such.

1**. Non-preferred drugs:** A PDL has been implemented by South Carolina Medicaid. Therapeutic classes included in the PDL may also be subject to PA requirements. A listing of drugs included in the PDL may be found at: http://southcarolina.fhsc.com.

> Prescribers are strongly encouraged to write prescriptions for "preferred" products. However, if a prescriber deems that the patient's clinical status necessitates therapy with a PA-required drug, the prescriber (or his/her designated office personnel) is responsible for initiating the PA request.

> A prospective, approved PA request will prevent rejection of prescription claims at the pharmacy due to the PA requirement.

2. The following home **or self-administered** injectable products (see *Important Note* which follows):

> A. Certain specified immunizing agents (i.e., influenza, pneumococcal, and Hepatitis-B vaccines; coverage guidelines are outlined in the Magellan Pharmacy Provider Manual).

> B. Growth hormone products such as Serostim®, Nutropin®, Norditropin®, Humatrope®, and Genotropin® (the prescriber should contact Magellan's Clinical Call Center at: +1 866 247 1181 or complete the South Carolina Medicaid Growth Hormone Prior Authorization Request form).

> Certain (rebated) injectable products, which are packaged and usually prescribed for home administration, are *routinely covered* by Medicaid. Therefore, those specified home-administered pharmaceuticals are not subject to PA nor do they require any special billing procedures. Routinely covered injectable products are: insulin; diabetic and epinephrine emergency kits; Imitrex®, Betaseron®, Avonex®, and Copaxone®.

> **Important Note:**

> Injectables administered in a physician's office, emergency room, infusion center or other clinical setting are not routinely covered under Pharmacy Services.

> Staff in the facility, infusion center, or office where the injectable drug is to be administered should contact the South Carolina Medicaid Provider Service Center at: +1 888 289 0709 to obtain Medicaid coverage, billing and reimbursement information.

<u>Exceptions</u>: Certain physician injectable drugs and injectables administered in a South Carolina Department of Mental Health outpatient clinic may be billed under the Pharmacy benefit. Due to safety and product stability issues, the pharmacy provider must deliver these pharmaceuticals *directly* to the physician's office or clinic.

For physician injectable products administered in the doctor's office or clinic and billed under the Pharmacy benefit, a PA may be required. In these cases, the prescriber must contact Magellan's Clinical Call Center at: +1 866 247 1181 to request approval.

3. **Medicare Part B — covered pharmaceuticals** (including their respective generics) for dually eligible beneficiaries. These products include:

   A. Immunosuppressants (e.g., CellCept®, Imuran®, Neoral®, Prograf®, Sandimmune®, Sangcya®, Simulect®, Zenapax®, Gengraf®, Rapamune®, Orthoclone OKT3®, and Atgam®)

   B. Chemotherapy agents (oral)

   C. Anti-emetics (oral)

   D. Inhalation drugs

   E. Interferon Beta-1A (Avonex®)

Providers must have a supplier billing number in order to bill *Medicare Part B* for immunosuppressant drugs. The Medicare supplier billing number may be obtained by calling the National Supplier Clearinghouse at: +1 866 238 9652 (toll-free). For those non-End-Stage Renal Disease (ESRD) transplant patients whose surgeries were sponsored by Medicare, coverage of immunosuppressants is a lifetime *Medicare Part B* benefit. Those beneficiaries who have received a kidney transplant and had Medicare entitlement solely due to ESRD, and have not become entitled to Medicare due to age or disability, are NOT eligible for lifetime Medicare Part B coverage of immunosuppressants. However, Medicare Part B does sponsor coverage of these drugs for ESRD patients for a 36-month period following the date of discharge from the hospital stay during which the Medicare-covered transplant surgery was performed. Medicare Part B should continue to be billed for reimbursement of immunosuppressants until the provider receives a denial of coverage. Once Medicare Part B denial of coverage for immuno-suppressive drug therapy is confirmed (or if Medicare Part <u>B</u> denies payment because the drug is considered non-covered for the diagnosis indicated), the pharmacist should then submit the claim to the beneficiary's Part <u>D</u> PDP.

Regarding oral chemotherapy agents for dually eligible beneficiaries, if the oral chemotherapy drug being prescribed is used to treat cancer, then the provider should bill *Medicare Part B* for reimbursement. If such a drug is ***not*** being used to treat cancer but rather some other medical condition, the provider should bill *Medicare Part <u>D</u>* for reimbursement.

Medicare Part B is the primary payer if the oral anti-emetic replaces an intravenous anti-emetic and the initial oral anti-emetic dose is administered within two hours of chemotherapy administration.

If Medicare Part B reimburses any portion of the Pharmacy Services provider's submitted charge (or if the claim paid amount was applied to the Medicare Part B annual deductible), the pharmacist may request PA to bill Medicaid secondarily using Magellan's POS system. Pharmacists may request PA by contacting the Magellan Clinical Call Center at: +1 866 247 1181 (toll-free). If the amount paid was applied toward the annual deductible, a copy of the Medicare Part B EOB must be faxed to the Magellan Clinical Call Center at +1 888 603 7696 (toll-free). Pharmacists are encouraged to indicate the beneficiary's 10-digit Medicaid identification number on Medicare EOBs furnished to Magellan. While subsequent fills for that specific drug therapy will continue to require PA, faxing additional copies of the Medicare EOB will not be necessary each time the prescription is refilled.

Providers should go to http://www.palmettogba.com for complete Medicare Part B policy and billing codes pertaining to covered outpatient pharmaceuticals (including inhalation drugs).

To facilitate claims submission, it may be necessary for the pharmacist to contact the prescriber for additional diagnostic or patient-specific information in order to determine which payer (Part B or Part D) should be billed as primary. (See the *Billing Guidance* section of this manual for billing instructions.)

4. **Sildenafil when prescribed for the treatment of pulmonary arterial hypertension.** The prescriber must contact Magellan's Clinical Call Center at: +1 866 247 1181 to communicate patient-specific clinical information. If coverage is approved, subsequent PA requests will be necessary at certain intervals for that specified therapy and dosage.

5. **Amphetamines** for patients over the age of 21 to treat: Adult Attention Deficit Disorder or narcolepsy.

   Note: Pharmaceuticals used as anorexiants are excluded from coverage. Amphetamines for FDA-approved indications for patients from birth to the date of their 21st birthday are routinely covered and do not require PA.

6. **Lactulose** solution used:

   A. As an adjunct to protein restriction and supportive therapy for the prevention and treatment of portal-systemic encephalopathy including hepatic pre-coma and coma, or

   B. In the treatment of chronic constipation *if trials with conventional laxative therapies have been unsuccessful.*

Note: Lactulose solution is non-covered if prescribed for the initial treatment of chronic constipation in lieu of trials with conventional laxative therapies.

7. **Tretinoin** used for patients over the age of 21 to treat:

   A. Acne vulgaris,

   B. Forms of skin cancer, or

   C. The following dermatologic conditions: lamellar ichthyosis, mollusca contagiosa, verrucae plantaris, verrucae planae juvenilis, ichthyosis vulgaris bullous congenital ichthyosiform and pityriasis rubra pilaris.

   Note: Pharmaceuticals used for cosmetic purposes are excluded from coverage; therefore, tretinoin is non-covered when prescribed for photoaged skin or skin conditions related to the normal aging process (e.g., wrinkles, liver spots). Tretinoin used for FDA-approved indications for patients from birth to the date of their 21st birthday is routinely covered and does not require PA.

   Lipase inhibitors (e.g., Xenical®) when prescribed for morbid obesity or hypercholesterolemia; in addition to meeting the conditions specified below, the patient must be at least 18 years of age. (The prescriber must contact Magellan's Clinical Call Center at: +1 866 247 1181 to request approval).

   Xenical® (orlistat) for diagnosis of morbid obesity:

   • Patient must have a diagnosis of obesity in the presence of other risk factors (e.g., hypertension, diabetes, dyslipidemia).

   • Patient must have an initial body mass index > 30 kg/m2.

   • Patient must be on a reduced fat and calorie diet with nutritional counseling regarding adherence to dietary guidelines.

   Xenical® (orlistat) for diagnosis of hyper-cholesterolemia:

   • Patient must have a diagnosis of hypercholesterolemia with treatment failures.

   • Patient must have experienced an adverse reaction as a direct result of *each* of the FDA-approved drug classes for treating hypercholesterolemia.

8. **Panretin® (alitretinoin)**

   The prescriber must contact Magellan's Clinical Call Center (+1 866 247 1181) to request approval; if approved, coverage may be granted for a period of four months. (There is a limit of one tube of Panretin® gel on the initial prescription.)

9. **Targretin® (bexarotene)**

   The prescriber must contact Magellan's Clinical Call Center (+1 866 247 1181) to request approval; if approved, coverage may be granted for a period of four months. (On the initial prescription, there is a limit of one tube of Targretin® gel *or* a one month's supply of oral medication.)

10. **Certain anti-ulcer products** (i.e., PPIs that are not included on the PDL.)

    The prescriber must contact Magellan's Clinical Call Center (+1 866 247 1181) to communicate patient-specific clinical information. If coverage of the requested product is approved, subsequent PA requests will be necessary at certain intervals for that specified therapy and dosage.

11. **Certain anti-arthritis products** (i.e., cyclooxygenase-2 [COX-2] inhibitors)

    The anti-arthritis PA program includes:

    • COX-2 inhibitors, all strengths and dosages.

    Note: PA is not required for COX-2 inhibitor prescriptions/refills for patients 60 years of age and greater.

    The prescriber must contact Magellan's Clinical Call Center (+1 866-247-1181) to communicate patient-specific clinical information. If coverage of the requested product is approved, subsequent PA requests will be necessary at certain intervals for that specified therapy; generally, PA approval for anti-arthritis drugs is in effect for up to one year.

Other Prior Authorization Protocols

Since non-clinical PAs generally may be processed successfully by the pharmacist at the POS, it is the pharmacist's responsibility to submit such claims in a timely and accurate fashion. To facilitate the claims submission process (e.g., to verify place of administration for injectable products), the pharmacist may have to contact the prescriber in order to obtain patient-specific diagnostic or related information.

Prescribers may request PA from Magellan via telephone, fax (+1 888 603 7696, toll-free), requests for PA will be responded to within 24 hours of receipt. (For expediency, telephonic requests are preferred.)

The SCDHHS requires that PA be requested (and subsequent approval entered into Magellan's system) prior to the dispensing of the medication; thus, retroactive PAs may be considered only in cases of retroactive Medicaid eligibility determination.

It should be noted that Magellan's PA process does not require a "PA number" to be entered on a POS (or paper) claim; the only requirement is that the PA record is activated in Magellan's system

prior to claim submission. Clinical PA timelines may vary, depending upon category of drug requested and patient-specific diagnostic information.

If the request for PA is denied, Magellan's Clinical Call Center staff will notify the originator of the request verbally at the time of telephonic contact or by fax if the request was made via that method.

For clinical PAs in which a Magellan pharmacy technician or pharmacist requests additional information from the prescriber, Magellan will deny the PA request if the prescriber does not respond to a request for information within three working days. Denial letters are not issued in such instances.

Hepatitis C

Hepatitis C drugs are covered under FFS Medicaid. PA requests for Hepatitis C medications should be submitted to Magellan's Clinical Call Center via telephone (+1 866 247 1181) or via fax (+1 888 603 7696).

OTHER SERVICE/PRODUCT LIMITATIONS

Drug Utilization Review Program

The Drug Utilization Review (DUR) program must ensure that prescribed medications are appropriate, medically necessary, and are not likely to result in adverse medical outcomes. The SCDHHS DUR program is composed of the: 1) retrospective DUR program, 2) prospective DUR component, 3) DUR Panel's responsibilities and drug history reviews, 4) patient counseling for Medicaid beneficiaries receiving prescriptions, and 5) records requirement of a pharmacy patient record system (see the *Records Requirements* section in this manual for detailed information regarding this specific component).

Retrospective DUR
The SCDHHS retrospective DUR program involves monthly reviews of patient drug history profiles by a panel of physicians and pharmacists. These monthly reviews seek to assist prescribers by focusing upon the possibility of adverse drug effects. Many clinical factors influence prescription decisions, including the patient's health status, side effects reported by the patient or detected by the prescriber, and available alternative treatments. Non-clinical factors also impact these reviews. To prescribe appropriately, the practitioner needs all relevant clinical and personal information, including the drugs ordered by other prescribers. Upon notification of a potential drug therapy problem, written notification is sent to the prescriber(s) and dispensing pharmacies. This notification describes the potential drug therapy problem and includes the comprehensive drug history profile.

The DUR Panel conducts a retrospective review of the patient drug history profiles and evaluates the drug history information for: therapeutic appropriateness, over and underutilization, appropriate use of generic products, therapeutic duplication, drug-disease contraindications, drug-drug interactions, incorrect dosage or duration of therapy, and clinical abuse/misuse. Providing practitioners with specific, focused and *comprehensive drug information* increases their awareness of potential drug therapy problems.

This allows prescribers to make any necessary prescription changes in order to prevent adverse outcomes.

Prospective DUR

Prospective DUR means a review of the patient's drug therapy and prescription drug order as part of a drug regimen review before each prescription is filled or dispensed. As an integral part of the POS system, ProDUR encompasses the detection, evaluation and counseling components of pre-dispensing drug therapy screening. The POS ProDUR system assists the pharmacist in these functions by addressing multiple situations in which potential drug problems may exist. DUR performed prior to dispensing helps pharmacists ensure that beneficiaries receive appropriate medications. This is accomplished by providing information that may not have been previously available to the dispensing pharmacist.

Because the ProDUR system examines previously paid claims from all participating pharmacies as it reviews a beneficiary's Medicaid-reimbursed prescription history, drugs that interact with or are affected by previously dispensed medications can be detected. The ProDUR system is offered as an informational tool to assist the pharmacist in performing his/her professional duties.

The potential problems that the ProDUR system detects include:

- Overutilization (i.e., early refill)

- Underutilization

- Excessive daily dose

- Insufficient daily dose

- Therapeutic duplication

- Drug-to-drug interaction

- Drug-age contraindication

- Drug-pregnancy contraindication

- Excessive quantity

- Drug-diagnosis contraindication

Non-computerized pharmacy providers (or those providers who choose not to utilize the POS system for claims submission) must manually screen each prescription for certain therapeutic problems, using standards consistent with OBRA 1990 requirements.

If the Medicaid POS ProDUR system is not utilized, SCDHHS' prospective DUR program requires that, in compliance with OBRA 1990 requirements, the pharmacist must perform a drug regimen review which includes, but is not limited to, the following activities:

1. Evaluation of prescription drug orders and pharmacy patient records for:

    A. Known allergies

    B. Rational therapy — contraindications

    C. Reasonable dose and route of administration

    D. Incorrect dosage or duration of therapy

    E. Reasonable directions for use

    F. Therapeutic appropriateness

    G. Appropriate use of generic products

2. Evaluation of prescription drug orders and pharmacy patient records for duplication of therapy and therapeutic duplication.

3. Evaluation of prescription drug orders and pharmacy patient records for interactions such as:

    A. Drug-drug

    B. Drug-food

    C. Drug-disease (if available)

    D. Adverse drug reactions

    E. Clinical abuse/misuse

4. Evaluation of prescription drug orders and pharmacy patient records for proper utilization, including overutilization or underutilization, and optimum therapeutic outcomes.

See the Prospective Drug Utilization Review section in the Magellan Pharmacy Provider Manual for additional information.

DUR Panel
The DUR Panel is a panel composed of physicians and pharmacists. This panel of health care practitioners has responsibilities pertaining to:

1. The retrospective DUR program, including the retrospective review of patient drug history profiles.

2. Criteria used in the retrospective DUR process and subsequent application of standards for both the retrospective and prospective DUR programs.

3. Decisions regarding interventions with prescribers and pharmacists in response to therapy problems identified through retrospective DUR.

6
REPORTING/DOCUMENTATION

MEDICAID COVERAGE OF GENERIC PRODUCTS

Medicaid does not cover brand name products for which there are therapeutically equivalent, less costly generics available unless documentation of a treatment failure is furnished.

Furthermore, **the treatment failure must be directly attributed to the patient's use of a generic for the brand name product**.

A South Carolina Medicaid MedWatch Form, completed by the prescriber and forwarded to the Magellan Clinical Call Center (toll-free fax number: +1 888 603 7696), serves as the required documentation of a treatment failure with a generic product. (See a copy of the South Carolina Medicaid MedWatch Form and a camera-ready copy located with the Forms information associated with this manual.) If the requested brand name product is not approved for Medicaid reimbursement, Magellan's Clinical Call Center staff will notify the prescriber. Conversely, if coverage of the product is approved, Medicaid will reimburse the patient's pharmacy, provided all other relevant program requirements are met; such PA approval is in effect for the duration of that specific therapy.

As stated above, Medicaid does not routinely cover brand name products for which there are therapeutically equivalent, less costly generics available **except** for the following brand name products (traditionally categorized as Narrow Therapeutic Index [NTI] drugs): digoxin, warfarin, theophylline (controlled release), levothyroxine, pancrelipase, phenytoin and carbamazepine.

Any of these pharmaceuticals, however, may be subject to upper limit of payment policies requiring prescriber certification for the use of the brand name product.

In addition to the South Carolina Medicaid MedWatch Form requirement (where indicated), the prescriber's *handwritten* notation on the prescription certifying "brand medically necessary" or "brand necessary" is the required mechanism by which Medicaid will reimburse for the specified brand name drug. Furthermore, in order to avoid recoupment of Medicaid monies, this certification must be present on the prescription *prior* to billing Medicaid for any brand medically necessary product.

Records Requirements — Types of Records

Records are defined as, but are not limited to the following: prescription drug orders, chart orders, annotations to identify the specific drug dispensed, drug invoices, annotations to reflect refills issued, retained copies of claims filed (if submitting non-POS claims), pharmacy patient record system per individual patient, and any other documentation required by state and federal laws or requirements. Additionally, specific claims payment and/or denial information pertaining to other third-party payers should be retained as part of the provider's records. Such COB documentation serves to substantiate

that the provider has made every effort possible to collect monies from all other third-party payers prior to submitting a claim to Medicaid.

A pharmacy patient record system must be maintained by all pharmacies for patients for whom prescription drug orders are dispensed. The pharmacy patient record system shall provide for the immediate retrieval of information necessary for the dispensing pharmacist to identify previously dispensed drugs at the time a prescription drug order is presented for dispensing.

Pharmacists are advised that a pharmacy patient record system should include the following information:

- Full name of the patient for whom the drug is intended

- Address and telephone number of the patient

- Patient's age or date of birth

- Patient's gender

- List of all prescription drug orders obtained by the patient at the pharmacy during the two years immediately preceding the most recent entry showing the prescription number, name, and strength of the drug, the quantity and date received, the number of refills given, the date of each refill, the identity and quantity of each refill if different from the prescribed quantity, the identity of the dispensing pharmacist and the name of the prescriber.

- Pharmacist's comments relevant to the individual's drug therapy, including any other information peculiar to the specific patient or drug and additional comments such as the refusal of the pharmacist's offer to counsel or the patient's refusal to provide information.

The pharmacist shall make a reasonable effort to obtain information from the patient or the patient's agent regarding any known allergies, drug reactions, idiosyncrasies and chronic conditions or disease states of the patient and the identity of any other drugs, including OTC drugs, or devices currently being used by the patient which may relate to ProDUR. This information shall be recorded in the patient's record.

An automated system that provides the information detailed in the *Records Requirements* portion of this manual and meets the requirements outlined in the South Carolina Pharmacy Practice Act may be utilized. Such an automated system shall have the capability of producing sight-readable information on all original and refill prescription drug orders and the pharmacy patient record system.

Records Requirements — Long-Term Care Facility Records

Copies of chart orders must be retained for post-payment review purposes either by the NF or by the pharmacy, as described in the information above. A chart order is defined as a lawful order from a practitioner for a drug or device for patients of a hospital or extended care facility. If requested, it is the pharmacy provider's responsibility to obtain these records for auditing purposes.

7
PRESCRIBING/DISPENSING LIMITATIONS

PRESCRIPTION LIMIT

Adult Medicaid beneficiaries in full-coverage eligibility categories are allowed unlimited prescriptions. The monthly prescription limit and the monthly prescription limit override option for adult beneficiaries will no longer be applicable. Unlimited prescriptions will continue to be provided for Medicaid beneficiaries under the age of 21.

Quantity of Medication Limits/Dose Optimization Program

Medicaid reimburses for a maximum one-month supply of medication per prescription or refill or for a days' supply commensurate with the smallest package size available. SCDHHS defines a one-month supply as a maximum 31-day supply per prescription for non-controlled substances.

Providers should refer to the South Carolina Controlled Substances Regulations promulgated by the SCDHEC for maximum quantity limitations on prescriptions for controlled substances.

Furthermore, certain pharmaceuticals are subject to maximum quantity limitations. Those products which have quantity limits may be found at: http://southcarolina.fhsc.com. The Quantity Limits listing is updated periodically; therefore, providers may find it beneficial to refer to the website for the most current information. The established maximum quantities are based upon a month's supply of medication. PA will be necessary for any quantity exceeding the established per month limitation. Prescribers should contact the Magellan Clinical Call Center at: +1 866 247 1181 (toll-free) to request PA.

SCDHHS operates a Dose Optimization program. The focus of the Dose Optimization program is improved patient compliance with drug therapy regimens, reduced potential for exceeding the maximum recommended dose as determined by the FDA, and decreased adverse drug events.

Dose Optimization is an enhancement to the current Quantity Limits program. Medications that may be indicated for once or twice daily dosing are identified and where clinically applicable, Dose Optimization edits limit the number of times the medication is dosed. This editing process does not interfere with the total daily dosage of the medication prescribed for the patient. Prescribers are asked to consider appropriate Dose Optimization guidelines when higher strengths of the drug are commercially available. For example, prescriptions authorized for two Aricept® 5 mg tablets daily should instead be authorized for the commercially available Aricept® 10 mg tablet with instructions of one tablet daily.

When clinically appropriate, SCDHHS encourages pharmacy providers to contact prescribers regarding those prescriptions where changes may be appropriate to conform to daily dosing limitations.

For those patients who require unique dosing regimens, pharmacy providers should ask the prescriber or the prescriber's designated office personnel to contact Magellan's Clinical Call Center at: +1 866 247 1181 to request PA. Those products subject to Dose Optimization may be found at http://southcarolina.fhsc.com. The Dose Optimization listing will be updated periodically; therefore, providers may find it beneficial to refer to the website for the most current information.

Refills

Refills are to be provided only if authorized by the prescriber, allowed by law, and should be in accordance with the best medical and pharmacological practices. Refill documentation should be accurate and easily accessible for post-payment review purposes. If a refill authorization is received orally, sufficient documentation must be present on the original prescription. However, in those refill instances where a new and separate prescription is necessary (i.e., controlled substance prescription), a new prescription must be issued in accordance with state and federal requirements. **Automatic Refill Programs shall not be utilized for South Carolina Medicaid beneficiaries.** A pharmacy provider shall not automatically generate refills for a South Carolina Medicaid beneficiary.

It is understood that certain circumstances may necessitate an early refill (e.g., change in dosage, stolen or damaged prescriptions, etc.). If the prescription is refilled early (i.e., before 75% of the medication should have been exhausted, according to the prescriber's directions), a ProDUR denial error message ("early refill 866-254-1669") will be returned via the POS system. When there are circumstances that justify an early refill, the pharmacist must request PA by contacting the Magellan Technical Call Center at the toll-free number indicated. Requests for "early refill" overrides must meet certain specified criteria; those not meeting the established criteria will be denied.

Substitution of Equivalent Drug Products

With respect to prescriptions reimbursed through the South Carolina Medicaid program, Medicaid beneficiaries for whom the pharmaceuticals are intended are deemed to have consented to substitution of a less costly equivalent generic product that will result in a cost savings to the South Carolina Medicaid program. Therefore, individual patient consent for substitution as stipulated in South Carolina Code of Laws 40-43-86 (H) (6) shall not be required.

Telephone Orders

Telephone prescriptions are permissible; however, those for "brand medically necessary" pharmaceuticals are required to be signed by the prescriber and must be appropriately certified as "brand medically necessary" prior to being billed to the Medicaid program. To facilitate adherence to this policy, the pharmacist may fax the prescription to the prescriber for signature and "brand medically necessary" certification. Providers are reminded that all state and federal requirements must be adhered to regarding the dispensing of telephone prescriptions.

Electronically Transmitted Prescriptions

Electronically transmitted prescription drug orders are reimbursable by Medicaid; however, such prescriptions must meet state and federal requirements.

Tamper-Resistant Prescription Pads

Medicaid-covered outpatient prescription and OTC drugs are reimbursable only if non-electronic prescriptions are issued on a tamper-resistant pad.

These new federal requirements result from amendments to section 1903(i) of the Social Security Act, as required by Section 7002(b) of the U.S. Troop Readiness, Veterans' Care, Katrina Recovery and Iraq Accountability Appropriations Act of 2007.

Electronic prescriptions meeting federal and state requirements are excluded from this requirement.

To be considered tamper-resistant, a prescription pad must contain, at least one of the following three characteristics:

- One or more industry-recognized features designed to prevent unauthorized copying of a completed or blank prescription form.

- One or more industry-recognized features designed to prevent the erasure or modification of information written on the prescription by the prescriber.

- One or more industry-recognized features designed to prevent the use of counterfeit prescription forms.

A prescription pad must contain all three characteristics to be considered tamper-resistant and Medicaid reimbursable.

This rule does apply to NF, intermediate care facilities for the intellectually disabled, and other residential-like facilities where their prescriptions are separately reimbursed by Medicaid and not included in the facility's rate.

In addition, the requirement does *not* apply to e-prescriptions transmitted to the pharmacy, prescriptions faxed to the pharmacy or prescriptions communicated to the pharmacy by telephone by a prescriber. The requirement does *not* apply to managed care entities when the managed care entity pays for the prescription.

To the extent permissible under state and federal law and regulation, this requirement does not restrict emergency fills of non-controlled or controlled substances for which a prescriber provides the pharmacy with a verbal, faxed, electronic or compliant written prescription(s) within 72 hours after the date on which the prescription(s) was issued.

Future post payment audits of pharmacy claims for Medicaid reimbursement, whether conducted by the SCDHHS Division of Program Integrity or any other agent, will review compliance with the above requirements.

Prescription Information Transfer

The one-time transfer of original prescription information for dispensing one refill is permissible between pharmacies in South Carolina, subject to state and federal requirements.

Redispensing of Medications

The policy concerning the re-use of drugs returned from patients is contained in state and federal requirements regarding the practice of pharmacy. Re-use of these items would constitute fraud unless the pharmacist documents these drugs by name, date of service, etc., and makes appropriate refund to the Medicaid program.

Due to federal drug rebate program issues, it is preferable to accomplish such "refunds" by claims reversal via the POS system rather than by check.

Once the original paid claim has been reversed (i.e., voided), the provider should immediately resubmit a "corrected" claim, reflecting the amended quantity dispensed and reduced usual and customary charge. If necessary, providers should consult Magellan's Technical Call Center staff (+1 866 254 1669) in order to facilitate the claims reversal/resubmission process.

Opioid Quantity Limits

For initial opioid prescriptions, a maximum dose of 90 Morphine milligram equivalents (MME) per day will be allowed. Doses higher than 90 MME will reject at the POS. This dosing limitation is based on the Centers for Disease Control and Prevention recommendations. For additional claims processing information, refer to the Magellan POS manual which can be found here: http://southcarolina.fhsc.com/Downloads/provider/SCRx_ProviderManual_POS.pdf.

8
BILLING GUIDANCE

QUANTITY OF MEDICATION LIMITS/DOSE OPTIMIZATION PROGRAM

Providers should note that SCDHHS requires the use of the "metric decimal" quantity on Medicaid pharmacy claims. **A "rounded" or "rounded up" number must NOT be submitted as the billed quantity when the dispensed amount is a fractional quantity.** *If the dispensed quantity is a fractional amount, then the billed quantity must accurately reflect the specific metric decimal quantity that is dispensed.*

Billing incorrect quantities negatively affects quarterly rebate invoice data and results in under- or over-payment to providers. Furthermore, mispaid claims due to inaccurate quantities are subject to post-payment review and when appropriate, recoupment of monies. Pharmacy providers must evaluate their software and billing processes in order to ensure that the prescription quantity that is billed to Medicaid accurately reflects the dispensed quantity. Billing inquiries should be directed to Magellan's Technical Call Center at +! 866 254 1669. (See the *Post Payment Reviews* section in this manual for additional information.)

Upper Limits of Payment for Certain Multiple Source Products

Maximum reimbursement rates for certain multiple source drugs (both legend and OTC) are set by CMS or by SCDHHS and cannot be exceeded. The entire listing of products having either a federal upper limit (FUL) of payment or a South Carolina Maximum Allowable Cost (SCMAC) may be found at http://southcarolina.fhsc.com. The maximum allowable cost (MAC) listing at: http://southcarolina.fhsc.com includes *all products*, either state or federally mandated, *with a MAC price* and *includes unit dose forms* of those products listed. This online MAC listing is continually monitored and updated to reflect any state or federal changes, additions or deletions.

Generic equivalents of products having an established FUL or SCMAC are subject to the respective upper limit of payment indicated. Thus, *all* products that contain the same active ingredient(s) and strength(s) are subject to the established pricing restriction.

Furthermore, FULs or SCMACs are applicable for sugar-free or alcohol-free products, provided they contain the same active ingredient(s) and strength(s) as those pharmaceuticals indicated on the MAC listing. Additionally, any product with an upper limit of payment restriction that is packaged in a specialized dosage or convenience pack (e.g., Sterapred®) is subject to the established FUL or SCMAC.

However, it should be further noted that in those instances where the Wholesale Acquisition Cost (WAC) + 0.8% for a given NDC is *lower* than the established FUL or SCMAC, the provider's reimbursement will be based upon that specific product's lower WAC + 0.8%. Furthermore, when the provider agrees to dispense and subsequently bill a prescription to the Medicaid program, Medicaid's

reimbursement must be accepted as payment in full. Under no circumstances may the patient be billed the difference between the submitted charge and Medicaid's reimbursement.

Providers are reminded that only *rebated products* (whether brand name or generic) may be considered for Medicaid reimbursement. Certain pharmaceuticals subject to upper limits of payment restrictions may have both legend and OTC packaging. Claims for most OTC pharmaceuticals may be transmitted routinely through Magellan's POS system. Providers are reminded that a valid prescription must be on file for all items reimbursed through the Pharmacy Services Program.

Unless PA has been approved for the brand name drug, reimbursement for products included on the MAC listing will be based upon the lowest per-unit price (whether SCMAC, ~~FUL,~~ or WAC + 0.8%) in effect on the date of service. (As indicated in *Medicaid Coverage of Generic Products*, PA of the brand name product is not necessary for certain specified NTI drugs; however, NTI drugs *are subject to the "brand necessary" or "brand medically necessary" certification requirements described below.*)

For those brand name products having an established ~~FUL or~~ SCMAC on the date of service, providers are reminded that in addition to the South Carolina Medicaid MedWatch Form requirement (where the prescriber must document the occurrence of a treatment failure that is attributable to the generic product), the prescriber's *handwritten* notation on the prescription certifying "brand medically necessary" or "brand necessary" is required. This certification must be present on the prescription *prior* to billing Medicaid for any brand medically necessary prescription.

If the "brand medically necessary" certification is absent from the face of the prescription, a dual-line prescription form does not satisfy the brand medically necessary certification requirement; the prescriber's signature on the "Dispense as Written" signature line does not satisfy the brand medically necessary certification requirement; nor does the prescriber's verbal authorization satisfy the "brand medically necessary" certification requirement. A "blanket" authorization does not satisfy the "brand medically necessary" certification requirement. Therefore, in order to avoid recoupment of Medicaid monies, care should be taken prior to billing to ensure that the appropriate certification is indicated on *each* prescription for those claims transmitted (and reimbursed) as brand medically necessary.

The pharmacist must only use the Dispense as Written (DAW) code of '1' to obtain higher Medicaid reimbursement when the prescriber certifies in his/her own handwriting that a specific brand is medically necessary for a particular patient.

If non-POS claims submission methods are utilized (and the provider fails to properly designate the claim as "brand medically necessary" where indicated), requests for manual adjustments of those paid claims will not be honored.

Providers should note the requirement that the NDC submitted to Medicaid for payment **must** be identical to the NDC listed on the package from which the prescription was dispensed. Submission of any other NDC is a violation of Medicaid policy.

Regardless of the reason (limitations in computer programming, software, etc.) that any such violations occur, providers should take immediate steps to correct the problem.

Only the specific manufacturer's NDC on the product actually dispensed may be submitted for payment. Similarly, although a provider may be willing to accept reimbursement based upon the SCMAC or FUL, a non-prior authorized brand name NDC should not be submitted *unless it is identical to the NDC indicated on the package from which the prescription was dispensed*.

"Brand medically necessary" claims (including those for NTI drugs) are subject to post-payment review by the SCDHHS Division of Program Integrity, and all pertinent documentation (e.g., prescriptions or chart orders containing the specified terminology in the prescriber's own handwriting) must be retained in the provider's records. Medicaid payment will be recouped for any claim so designated if the prescriber's certification is not present on the prescription. (See the "Brand Medically Necessary" Prescriptions section within this manual.)

Prescription Origin Code

SCDHHS requires that the prescription origin code be submitted on pharmacy claims for new prescriptions. The following values will be accepted in NCPDP field 419-DJ:

1. Written

2. Telephone

3. Electronic

4. Facsimile

5. Pharmacy

Claims with this field left blank or submitted with a "0" (not specified) will reject.

Payment Methodology Information

The pharmacy provider should submit the pharmacy's usual and customary charge when billing Medicaid. The amount reimbursed by Medicaid for a drug dispensed **shall not exceed the lowest of:**

- ~~The FUL for the drug, if any, plus the current dispensing fee as established by the SCDHHS in accordance with federal requirements.~~

- **SCMAC** plus the current dispensing fee as established by the SCDHHS in accordance with federal requirements.

- **The WAC** plus 0.8%, plus the current dispensing fee as established by the SCDHHS in accordance with federal requirements.

Note: The WAC used in calculating the WAC price is furnished weekly to Magellan by a contracted pricing source. The NDC number used in billing Medicaid must be the NDC number contained on the package from which the drug was actually dispensed. Non-compliance with this policy may result in the recoupment of Medicaid monies.

SC AAC plus the current dispensing fee as established by the SCDHHS in accordance with federal requirements.

Note: The AAC is defined as the National Average Drug Acquisition Cost (NADAC). In those instances where the NADAC does not exist, the AAC is defined as Wholesale Acquisition Cost (WAC) minus 0 percent. Updates to the SC AAC rate used for reimbursement to providers are furnished by a contracted pricing source weekly. The NDC number used in billing Medicaid must be the NDC number contained on the package from which the drug was actually dispensed. Non-compliance with this policy may result in the recoupment of Medicaid monies.

- **The provider's usual and customary charge** to the general public for the prescription as written for the brand actually dispensed. (If the provider's submitted charge for a medication is less than Medicaid's calculated reimbursement, the system will subtract any applicable copayment from the submitted charge and pay the provider the difference).

  Note: When a pharmacist submits a "partial fill" prescription to Medicaid, the beneficiary's copayment and the pharmacist's dispensing fee will be prorated based on the fractional percentage of the quantity dispensed compared to the quantity prescribed. The pharmacy should only do a partial fill if there is a shortage of the drug and the pharmacy does not have enough in stock to fill the prescription.

Copayment

Providers are responsible for collecting applicable copayments and may not refuse service to a beneficiary due to his/her inability to pay copayment at the time the service is rendered. However, an inability to pay at the time of dispensing does not relieve the beneficiary of the responsibility for the copayment amount. The amount of the copayment will be deducted from the Medicaid reimbursement for all claims to which copayment applies.

Copayments are no longer required on certain diabetes, behavioral health, cardiovascular, anti-retroviral, anticonvulsant and smoking cessation products.

Following is a listing of those beneficiary groups and/or services that are exempt from the collection of copayment:

- Beneficiaries from birth to the date of their 19th birthday.

- Beneficiaries residing in long-term care facilities (NFs, Intermediate Care Facilities for Individuals with Intellectual Disabilities [ICF/IID]) (exemption does not apply to beneficiaries residing in adult residential care facilities/boarding homes or retirement homes).

- Beneficiaries receiving the Medicaid hospice benefit.

- Beneficiaries enrolled under the Family Planning Program pay category.

- Beneficiaries who are pregnant (verified by either the patient or prescriber). Pharmacy providers must enter a "2" in the *Prior Authorization Type Code* field in order to identify the prescription as copayment-exempt. (The previous policy exempting copayment only for those prescriptions annotated as "related to pregnancy" or "pregnancy-related" has been replaced with this policy, which exempts pregnant beneficiaries from any copayment requirements.)

- Beneficiaries who are members of the Health Opportunity Account Program.

- Beneficiaries who are members of a Federally Recognized Indian Tribe.

Since the collection of copayment was established to supplement the dispensing fee, compassionate waiver of copayment shall be limited to a case-by-case basis. Non-compliance by a provider may subject his or her reimbursement to adjustment.

Note: When a pharmacist submits a "partial fill" prescription to Medicaid, the beneficiary's copayment and the pharmacist's dispensing fee will be prorated based on the fractional percentage of the quantity dispensed compared to the quantity prescribed.

Regarding COBs claims, no third-party insurer copayments should be collected from beneficiaries if the claim is for a covered Medicaid product. Only the South Carolina Medicaid copayment (if applicable) should be collected from the beneficiary.

Claims for injectable medications covered by the Pharmacy Program that have a route of administration of "intravenous" and require multiple fills of the same drug (same dosage form and strength) will only require one copayment per calendar month.

Claims Submission for Certain Physician-Injectable Products

Pharmacy providers may bill South Carolina Medicaid for certain physician-injectable products (in lieu of physicians having to "buy and bill") when the product is administered to a patient in the physician's office or clinic. This billing option is applicable for services provided to non-dually eligible, Medicaid FFS beneficiaries only, and is not applicable for beneficiaries enrolled in a Medicaid MCO.

Due to safety and product stability issues, the pharmacy provider must ensure that the pharmaceutical is delivered *directly* to the physician's office/clinic.

Reimbursement Guidelines for Influenza, Rabies and Pneumococcal Vaccines

Regarding long-term care patients, the *Medicare Part B* program covers the administration of influenza and pneumococcal vaccines when furnished in compliance with any applicable State law by a provider of the services having a supplier number. Medicaid will not directly reimburse pharmacy providers for such vaccines where the long-term care patient is dually eligible for both Medicare and Medicaid coverage. However, for those long-term care patients having *only Medicaid coverage*, SCDHHS reimburses for the influenza virus, pneumococcal, rabies and Tdap (Tetanus, Diphtheria and Pertussis) vaccines. Reimbursement for the influenza virus is limited to no more than one vaccine per beneficiary per flu season (i.e., 270 consecutive days). After the initial pneumococcal vaccine is administered to an adult beneficiary, coverage for any necessary revaccination will be considered on a case-by-case basis. Rabies vaccines are covered for all FFS Medicaid beneficiaries with no restrictions.

Based on the recommendations of the Advisory Committee on Immunization Practices (ACIP), adults 19 years of age and older who have not previously received Tdap may receive a single dose. The ACIP also recommends that a single dose of Tdap be given to adults who have close contact with infants under 12 months of age, and health care personnel who work in hospitals or ambulatory care settings and have direct patient contact.

Furthermore, those pharmacists with special certification to administer immunizations may submit claims to the Medicaid Pharmacy Services Program for the *in-store administration* of influenza, pneumococcal, rabies and Tdap vaccines. Such claims must be submitted using the provider's NPI. Reimbursement is limited to beneficiaries 19 years of age and older who have only Medicaid coverage; claims for those patients who are eligible for both Medicare and Medicaid must be billed to Medicare Part B.

Note: Medicaid cannot be billed secondarily for Medicare Part B-covered vaccines. In those instances, the beneficiary's Medicare Part D PDP must be billed for any allowable secondary payment.

Providers who have Medicare Part B reimbursement questions or who wish to obtain an enrollment application in order to request assignment of a Medicare Part B supplier number should contact the Medicare Part B Customer Service Center at: +1 866 238 9654. It should be noted that a durable medical equipment regional carrier supplier number cannot be used to transmit vaccine claims that are covered under Part B Medicare.

Pharmacy Services and Third-Party Liability (TPL)

The Division of Third-Party Liability identifies Medicaid beneficiaries having health insurance coverage in order to have that insurance pay for services primary to Medicaid. Providers utilizing the POS system for claims submission should receive immediate confirmation of other third-party coverage if a claim rejects for that reason. (Providers who do not use the POS system must contact Magellan's Technical Call Center staff to obtain insurance verification and details regarding other TPL coverage.) **Since Medicaid is the payer of last resort, the provider MUST request payment from any**

available third-party resource (including Medicare Part B) and may bill Medicaid only after third-party payment is made or denied.

Note: If Medicare Part <u>B</u> denies payment because the drug is considered non-covered for the diagnosis indicated, the claim should then be submitted to the beneficiary's Medicare Part <u>D</u> PDP. Regarding PDP non-covered drugs, providers should be aware that South Carolina Medicaid will **not** be a secondary payer for products such as a PDP's non-formulary or non-preferred drug or a PDP's PA-required drug.

If the provider submits a claim to Medicaid prior to billing the responsible third-party payer(s), the claim will reject (NCPDP edit 41) and will not be processed further until the provider either indicates the amount paid by the other third-party payer(s) or is able to substantiate payment denial by the other third-party carrier(s).

If it is determined that the provider is not fully complying with this claims submission policy, recoupment of the Medicaid monies will result.

If the POS system is used to transmit claims to Medicaid and the "submit to primary carrier" error message is returned, additional messaging information regarding the appropriate carrier code (unique five-digit code which identifies the insurance company), the patient's policy number, and the carrier name will be furnished online to the provider to facilitate submission of the claim to the designated third-party payer(s). A list of unique five-digit carrier codes may be found at: http://southcarolina.fhsc.com/.

Furthermore, where necessary, providers may contact Magellan's Technical Call Center staff to obtain relevant health insurance information. It should be noted that a beneficiary may have more than one active other insurance policy. Subsequent carrier code/policy information will be displayed via the POS system until all active insurance coverage is exhausted. *No primary insurer copayments or deductible amounts should be collected from beneficiaries if the claim is for a Medicaid-covered product. Only the South Carolina Medicaid copayment (if applicable) should be collected from the beneficiary.* Billing questions regarding appropriate "other coverage" coding, etc., where other third-party insurance is involved may be directed to Magellan's Technical Call Center staff at: +1 866 254 1669.

When an insurance coverage has lapsed and the patient or provider has sufficient documentation to validate the termination date, such information (annotated to include the beneficiary's 10-digit health insurance number) should accompany a completed *Health Insurance Information Referral Form*; the application of a "lapse date" to the beneficiary's insurance record will facilitate timely claims processing and payment. Completed documents may be faxed to Medicaid Insurance Verification Services at: +1 803 252 0870. Additionally, the *Health Insurance Information Referral Form* may be used to furnish information to SCDHHS staff regarding potential private health insurance coverage not yet reflected in the database. (A sample *Health Insurance Information Referral Form* may be found with the Forms information, associated with this manual and linked within *Program Overview section*.)

Providers should refer to the Pharmacy Services and Third-Party Liability section of this manual for additional TPL-related information. The Magellan Pharmacy Provider Manual also contains detailed claims filing instructions regarding COBs/TPL.

Retroactive Medicaid Eligibility Reimbursement Issues

When a patient becomes retroactively eligible for Medicaid coverage, pharmacists may subsequently choose to bill Medicaid for reimbursement.

(This is a *voluntary* practice; in such cases, the provider is not obligated to submit claims to the Medicaid program.) Often, however, these patients have already paid for prescriptions dispensed prior to their retroactive eligibility determination. In these instances, if the provider *chooses* to bill Medicaid in order to make appropriate refunds to the patient, Medicaid's reimbursement is payment in full. The provider may only keep any applicable Medicaid copayment. (See the Provider Administrative and Billing Manual for additional policy regarding retroactive eligibility.)

Post Payment Reviews

Post-payment reviews of documentation, program compliance, and billing procedures are conducted by the Division of Program Integrity. Many of the discrepancies cited could be avoided by adhering to the policies and procedures outlined in the Medicaid Pharmacy Services Provider and Magellan Pharmacy Provider Manuals and state and federal requirements regarding the practice of pharmacy. The following topics represent some of the most common discrepancies identified during post payment reviews:

Tamper-Resistant Prescription Pads

Pharmacies that receive Medicaid reimbursement for written, non-electronic outpatient prescriptions and/or their refills, issued on prescription pads that do not meet the specified criteria for tamper-resistant or those that were not exempt from the criteria, will be required to repay the full Medicaid reimbursement for the prescription(s).

"Brand Medically Necessary" Prescriptions

The use of the "Brand Medically Necessary" claims filing designation (i.e., DAW code of '1') affects reimbursement only for those brand name products with upper limits of payment restrictions (i.e., FUL or SCMAC) established for that date of service. The pharmacist must only use the DAW code of '1' to obtain higher Medicaid reimbursement when the prescriber certifies *in his/her own handwriting* that a specific brand is medically necessary for a particular patient. The handwritten phrase "brand necessary" or "brand medically necessary" must appear on the face of the prescription. A dual line prescription blank (e.g., signing on the "Dispense as Written" line) does not satisfy the brand medically necessary requirement, nor does a blanket statement from the prescriber stating that the patient must have a brand name product satisfy this federal requirement.

The *prescriber's* (*not* his or her staff or agent's) handwritten notation on the prescription certifying "brand necessary" or "brand medically necessary" is the only permissible means for obtaining Medicaid reimbursement for the brand name product.

Therefore, in order to avoid recoupment of Medicaid monies, care should be taken ***prior*** to billing (i.e., prescriber must complete the South Carolina Medicaid MedWatch Form and certify the prescription as "brand necessary" or "brand medically necessary") to ensure that *appropriate claims filing procedures have been followed*.

Note: Those brand name NTI drugs having an established FUL or SCMAC on the date of service do ***not*** require PA via approval of the South Carolina Medicaid MedWatch Form; however, NTI drugs are subject to the "brand necessary" or "brand medically necessary" certification requirements outlined above. Prescriptions for NTI drugs which are not properly annotated are subject to post-payment review and recoupment of Medicaid monies.

Quantity of Medication
The quantity dispensed must not exceed the total quantity ordered by the prescriber. Additionally, the quantity dispensed and the quantity billed must agree.

Generally, to avoid prescription splitting and unnecessary use of the adult beneficiary's limited number of monthly prescriptions, if a prescription is written for an amount sufficient for a 30-day supply, no less than a 30-day supply may be billed to the Medicaid program. However, due to issues regarding drug stability or patient safety, some exceptions to this policy are deemed reasonable (e.g., clozapine therapy, C-IIs, etc.). If the provider does not have enough stock on hand to fill a prescription as written, he or she may submit a POS claim indicating the partial quantity dispensed. (Detailed information regarding partial fill functionality may be found in the Magellan Pharmacy Provider Manual.) If a non-POS method of claims submission is used, billing Medicaid should be deferred until the entire quantity ordered by the prescriber has been dispensed to the beneficiary.

The Medicaid program reimburses for a maximum one-month supply of medication per prescription or refill or for a day's supply commensurate with the smallest package size available. The SCDHHS defines a one-month supply as a maximum 31-day supply per prescription for non-controlled substances. Providers should refer to the South Carolina Controlled Substances Regulations promulgated by the SCDHEC for maximum quantity limitations on prescriptions for controlled substances.

No Written Record of Prescription
Providers must maintain original prescription documents in one of the three required appropriate prescription files. These documents must be readily retrievable and retained according to Medicaid policy and State pharmacy law. Providers are reminded that all state and federal requirements must be adhered to regarding prescription documentation and authenticity of records. Prescription records function as proof of services rendered, and it is the pharmacy provider's responsibility to retain these records for auditing purposes.

Additionally, providers are cautioned not to retroactively reproduce lost or misplaced original prescription documents. Upon proof of such activity, further administrative actions or sanctions may

be taken, including recoupment of Medicaid monies and suspension or termination from the Medicaid program.

Use of Valid Prescriber Identification Numbers

It is imperative that pharmacy providers submit valid prescriber identification numbers when submitting pharmacy claims. The submission of valid prescriber identification information on pharmacy claims is a critical component of provider participation in the Medicaid program. DUR, federal drug rebate data, and various Medicaid reporting systems are dependent upon the accuracy of information submitted on pharmacy claims. Therefore, the reporting of inaccurate or invalid prescriber identification numbers adversely impacts the effectiveness and reliability of many programs. If it is determined that the provider is not complying with this policy, recoupment of Medicaid monies will result. Reference detailed information in the Provider Administrative and Billing Manual regarding the proper use and submission of the prescriber's designated identification number.

Refills

Refills are to be provided only if authorized by the prescriber, allowed by law, and should be in accordance with the best medical and pharmacological practices. Refills must not exceed the number authorized by the prescriber. Refill documentation must be accurate and easily accessible for post-payment-payment purposes. If a refill authorization is received orally, sufficient documentation must be present on the original prescription. At least 75% of the current prescription must be used (according to the prescriber's directions) prior to submitting a refill claim for Medicaid payment. In those instances, where a refill requires a new and separate prescription (i.e., controlled substances), a new prescription must be issued in accordance with state and federal requirements.

SCDHHS requires that 85% of a narcotic prescription must be used (according to the prescriber's directions) prior to a new prescription being filled.

Automatic Refill Programs shall not be used for South Carolina Medicaid beneficiaries. A pharmacy provider shall not automatically generate refills for South Carolina Medicaid beneficiaries.

Package Size/Unit-Dose Packaging

Providers *must* bill Medicaid using the NDC number that reflects the actual package size from which the medication was dispensed and the original prescription or the patient profile documents such. Manufacturer rebate payments to the State are based on prescription claim payment data by NDC number. To assure that the appropriate manufacturer is billed for the rebate, it is imperative that pharmacists take care to correctly identify the NDC number (and thus the package size) of the pharmaceutical dispensed.

Providers may be required to furnish invoice documentation to substantiate claims information billed to Medicaid. Failure to adhere to this policy will result in the recoupment of Medicaid monies.

The dispensing of unit-dose packaging to the general public is strongly discouraged and should be restricted to those individuals residing in an institutional setting (e.g., NF, ICF-IID, residential care

facility or boarding home). Furthermore, if medication is re-packaged by the provider prior to dispensing or delivery, Medicaid beneficiaries may *not* be charged a repackaging fee.

340B Program

Effective with dates of service on or after July 1, 2019, the following policy will apply regarding the submission of claims for drugs purchased through the 340B Program, as described in Section 340B of the Public Health Act of 1992.

For drugs purchased through the 340B Program, covered entities must submit a value of "20" in the Submission Clarification Code field (420-DK). When submitting Medicaid FFS claims, an amount not to exceed the 340B ceiling price plus an enhanced 340B dispensing fee should be submitted in the usual and customary field.

Claims submitted by covered entities without a value of "20" in the Submission Clarification Code field will be considered eligible for Medicaid rebates. This policy applies to all covered entities, regardless of designation by the Health Resources and Services Administration (HRSA) Office of Pharmacy Affairs.

For claims with dates of service prior to July 1, 2019, SCDHHS will continue to use the HRSA Medicaid Exclusion File to determine whether covered entities dispense drugs purchased through the 340B Program to Medicaid beneficiaries. Once a covered entity has been designated appropriately by HRSA, SCDHHS will take the necessary actions to exclude these claims from the Medicaid Drug Rebate Program. Any providers whose information is not correctly included in the HRSA Medicaid Exclusion File should submit their NPI number and 340B designation to SCDHHS at: pharmacy@scdhhs.gov.

HRSA guidance provides additional restrictions on the use of drugs purchased under the 340B Program for Medicaid beneficiaries when they are dispensed by contract pharmacies. Specifically, HRSA requires that the covered entity, the contract pharmacy and the State Medicaid agency have an arrangement to prevent duplicate discounts, with that arrangement being reported to HRSA. As no such arrangements exist for the South Carolina Medicaid program, contract pharmacies must carve out Medicaid beneficiaries.

Additional information may be found in the Magellan POS manual which can be found here: http://southcarolina.fhsc.com/Downloads/provider/SCRx_ProviderManual_POS.pdf.