COMMONWEALTH of VIRGINIA
Office of the Attorney General

Mark R. Herring
Attorney General

900 East Main Street
Richmond, Virginia 23219
804-786-2071
FAX 804-786-1991
Virginia Relay Services
800-828-1120

MEMORANDUM

TO: **EMILY MCCLELLAN**
Regulatory Supervisor
Virginia Department of Medical Assistance Services

FROM: **USHA KODURU** UK
Assistant Attorney General

DATE: **February 23, 2021**

SUBJECT: **12 VAC 30-10-650 Fast-Track Regulation to Update Drug Utilization Review Program (5514/8942)**

I am in receipt of the attached regulation to update language related to the Drug Utilization Review Program in accordance with the Support Act (Public Law No. 115-271). You asked the Office of the Attorney General to review and determine if DMAS has the legal authority to promulgate this regulation and if the regulation comports with state and federal law.

Based on my review, it is my view that the Director, acting on behalf of the Board of Medical Assistance Services pursuant to Virginia Code §§ 32.1-324 and 325, has the authority to promulgate this regulation subject to compliance with the provisions of Article 2 of the Administrative Process Act and has not exceeded that authority. This regulation amends the State Plan and approval by the Centers for Medicare and Medicaid Services must be granted.

Pursuant to Va. Code § 2.2-4012.1, if an objection to the use of the fast-track process is received within the public comment period from 10 or more persons, any member of the applicable standing committee of either house of the General Assembly or of the Joint Commission on Administrative Rules, DMAS shall (i) file notice of the objection with the Registrar of Regulations for publication in the Virginia Register, and (ii) proceed with the normal promulgation process set out in this article with the initial publication of the Fast-Track regulation serving as the Notice of Intended Regulatory Action.

If you have any questions or need additional information about this regulation, please contact me at 786-4074.

cc: Kim F. Piner, Esquire

Attachment

Proposed Text

12VAC30-10-650. Drug Utilization Review Program.

A. 1. The Medicaid agency meets the requirements of § 1927(g) of the Act for a drug use review (DUR) program for outpatient drug claims.

2. The DUR program assures that prescriptions for outpatient drugs are:

—a. Appropriate

——b. Medically necessary

—c. Are not likely to result in adverse medical results

B. The DUR program is designed to educate physicians and pharmacists to identify and to reduce the frequency of patterns of fraud, abuse, gross overuse, or inappropriate or medically unnecessary care among physicians, pharmacists, and patients or associated with specific drugs as well as:

—1. Potential and actual adverse drug reactions

——2. Therapeutic appropriateness

——3. Overutilization and underutilization

——4. Appropriate use of generic products

——5. Therapeutic duplication

——6. Drug disease contraindications

——7. Drug-drug interactions

——8. Incorrect drug dosage or duration of drug treatment

——9. Drug allergy interactions

—10. Clinical abuse/misuse

11. Provisions of Section 1004 of the SUPPORT ACT (below)

C. SUPPORT ACT Provisions

1. Claim Review Limitations

a. Prospective safety edits including early, duplicate fill, and quantity limits for clinical appropriateness for opioids.

b. Maximum daily Morphine Milligram Equivalents (MME) safety edits: A maximum dosing limit on opioids limits the daily morphine milliequivalents (as recommended by clinical guidelines)

c. Concurrent Utilization Alerts: Prospective drug to-drug interaction alerts will require a response from the pharmacy if an opioid and benzodiazepine or opioid and antipsychotics are being dispensed within an overlapping period with retrospective reviews performed on an ongoing periodic basis.

d. Comprehensive Retrospective DUR is performed on opioid prescriptions on an ongoing periodic basis.

2. Programs to Monitor Antipsychotic Medications to Children. Antipsychotic agents are reviewed for age appropriateness, duplicate therapy, and adverse effects in children based on the FDA product approval and clinical guidelines.

3. Fraud and Abuse Identification. The Client Medical Management (CMM) program for fee-for-service (FFS) beneficiaries that may require restriction to physician, pharmacy or both limiting the beneficiary's access to services identified as not medically necessary, excessive or both. The beneficiary's designated physician is

responsible for supervising, coordinating, and providing initial and primary medical care; initiating written referrals for specialist care and for maintaining the continuity of patient care.

~~C.~~ D. The DUR program shall assess data use against predetermined standards whose source materials for their development are consistent with peer-reviewed medical literature which has been critically reviewed by unbiased independent experts and the following compendia:

American Hospital Formulary Service Drug Information (2003, as amended)

United States Pharmacopeia-Drug Information (2003, as amended)

MICROMEDEX (as updated monthly)

Drug Facts and Comparisons (as updated monthly)

Drug Information Handbook (2003, as amended in 2004)

~~D.~~ E. DUR is not required for drugs dispensed to residents of nursing facilities that are in compliance with drug regimen review procedures set forth in 42 CFR 483.60. The state has nevertheless chosen to include nursing home drugs in retrospective DUR.

~~E.~~ F. 1. The DUR program includes prospective review of drug therapy at the point of sale or point of distribution before each prescription is filled or delivered to the Medicaid recipient.

2. Prospective DUR includes screening each prescription filled or delivered to an individual receiving benefits for potential drug therapy problems due to:

~~—~~Therapeutic duplication

~~—~~Drug disease contraindications

~~—~~Drug-drug interactions

~~—~~Drug-interactions with nonprescription or over-the-counter drugs

~~—~~Incorrect dosage or duration of drug treatment

~~—~~Drug allergy interactions

~~—~~Clinical abuse/misuse

3. Prospective DUR includes counseling for Medicaid recipients based on standards established by State law and maintenance of patient profiles.

4. Prospective DUR may also include electronic messages as well as rejection of claims at point-of-sale pending appropriate designated interventions by the dispensing pharmacist or prescribing physician.

5. Designated interventions may include provider override, obtaining prior authorization via communication to a call center staffed with appropriate clinicians, or written communication to prescribers.

~~F.~~ G. 1. The DUR program includes retrospective DUR through its mechanized drug claims processing and information retrieval system or otherwise which undertakes ongoing periodic examination of claims data and other records to identify:

~~—~~Patterns of fraud and abuse

~~—~~Gross overuse

~~—~~Inappropriate or medically unnecessary care among physicians, pharmacists, Medicaid recipients, or associated with specific drugs or groups of drugs.

2. The DUR program assesses data on drug use against explicit predetermined standards including but not limited to monitoring for:

~~—~~Therapeutic appropriateness

—Overutilization and underutilization

—Appropriate use of generic products

—Therapeutic duplication

—Drug disease contraindications

—Drug-drug interactions

—Incorrect dosage/duration of drug treatment

—Clinical abuse/misuse

3. The DUR program through its state DUR Board, using data provided by the board, provides for active and ongoing educational outreach programs to educate practitioners and pharmacists on common drug therapy problems to improve prescribing and dispensing practices.

4. In situations of conflict with these criteria, DMAS, pursuant to the DUR Board's criteria and requirements, shall reject or deny presented claims and require the dispensing pharmacist to intervene as specified through electronic messages in the point-of-sale system before the claim will be approved for payment.

5. Designated interventions may include provider override, obtaining prior authorization via communication to a call center staffed with appropriate clinicians, or written communication to prescribers.

~~G.~~ H. 1. The DUR program has established a state DUR Board directly.

2. The DUR Board membership includes health professionals (one-third licensed actively practicing pharmacists and one-third but no more than 51 percent licensed and actively practicing physicians) with knowledge and experience in one or more of the following:

—Clinically appropriate prescribing of covered outpatient drugs.

—Clinically appropriate dispensing and monitoring of covered outpatient drugs.

—Drug use review, evaluation and intervention.

—Medical quality assurance.

3. The activities of the DUR Board include:

—Prospective DUR

—Retrospective DUR

—Application of Standards as defined in § 1927(g)(2)(C), and

—Ongoing interventions for physicians and pharmacists targeted toward therapy problems or individuals identified in the course of retrospective DUR

4. The interventions include in appropriate instances:

—Information dissemination

—Written, oral, and electronic reminders

—Face-to-Face and telephonic discussions

—Intensified monitoring/review of prescribers/ dispensers

—Rejected or denied claims, as appropriate, to prevent the violation of the DUR Board's predetermined criteria.

—Provider override, obtaining prior authorization via communication to a call center staffed with appropriate clinicians, or written communication to prescribers.

~~H.~~ I. The state assures that it will prepare and submit an annual report to the secretary, which incorporates a report from the state DUR Board, and that the state will adhere to the plans, steps, procedures as described in the report.

The Medicaid agency ensures that predetermined criteria and standards have been recommended by the DUR Board and approved by either BMAS or the director, acting on behalf of the BMAS, pursuant to § 32.1-324 of the Code of Virginia and that they are based upon documentary evidence of the DUR Board. The activities of the DUR Board and the Medicaid fraud control programs are and shall be maintained as separate. The DUR Board shall refer suspected cases of fraud or abuse to the appropriate fraud and abuse control unit with the Medicaid agency.

~~I.~~ J. 1. The state establishes, as its principal means of processing claims for covered outpatient drugs under this title, a point-of-sale electronic claims management system to perform on-line:

a. Real time eligibility verification.

b. Claims data capture.

c. Adjudication of claims. Such adjudication may include the rejection or denial of claims found to be in conflict with DUR criteria. Should such rejection or denial occur during the adjudication process, the dispensing pharmacist shall have the opportunity to resolve the conflict and resubmit the claim for readjudication.

d. Assistance to pharmacists, etc., applying for and receiving payment.

2. Prospective DUR is performed using an electronic point of sale drug claims processing system.

~~J.~~ K. Hospitals which dispense covered outpatient drugs are exempted pursuant to federal law from the drug utilization review requirements of this section when facilities use drug formulary systems and bill the Medicaid program no more than the hospital's purchasing cost for such covered outpatient drugs.