



STATE OF DELAWARE
STATE COUNCIL FOR PERSONS WITH DISABILITIES

MARGARET M. O'NEILL BUILDING
410 FEDERAL STREET, SUITE 1
DOVER, DE 19901

VOICE: (302) 739-3620
TTY/TDD: (302) 739-3699
FAX: (302) 739-6704

MEMORANDUM

DATE: March 28, 2014

TO: Ms. Sharon L. Summers, DMMA
Planning & Policy Development Unit

FROM: Daniese McMullin-Powell, Chairperson
State Council for Persons with Disabilities

RE: 17 DE Reg. 887 [DMMA Proposed Adult Group Medicaid Claiming Methodology Regulation]

The State Council for Persons with Disabilities (SCPD) has reviewed the Department of Health and Social Services/Division of Medicaid and Medical Assistance's (DMMA's) proposal to adopt an amendment to the Medicaid State Plan regarding the Federal Medical Assistance Percentage (FMAP) effective January 1, 2014. The proposed regulation is published as 17 DE Reg. 887 in the March 1, 2014 issue of the Register of Regulations.

As background, the Affordable Care Act (ACA) contemplates State Medicaid programs covering individuals with countable income up to 133 percent of the poverty level. Delaware Medicaid already covered this population and Delaware therefore qualifies as an "expansion state". In order to qualify for an enhanced federal Medicaid match for covering this group of individuals, the State must adopt a Medicaid Plan amendment based on a CMS template. The federal Medicaid match for expansion states is described at the top of p. 889. DMMA envisions the receipt of the following federal funds based on the initiative: \$78,254,636 in FFY 14 and \$137,495,659 in FFY15.

SCPD endorses the proposed regulation since the Plan amendment is designed to achieve conformity with CMS guidance under the ACA.

Thank you for your consideration and please contact SCPD if you have any questions or comments regarding our position or observations on the proposed regulation.

cc: Mr. Stephen Groff
Mr. Brian Hartman, Esq.
Governor's Advisory Council for Exceptional Citizens
Developmental Disabilities Council

After review of the proposed regulation, SCPD wanted to note that pharmacies have balked at low drug reimbursement rates in the past. See attached 8 DE Reg. 961-962 (February 1, 2003). Cf. attached “How Medicaid Is Squeezing Specialty Pharmacy Profits” (February 18, 2014). However, Council is unable to adopt a position on the proposed regulation given lack of information on whether the rates fairly compensate pharmacies. The effective date of the Plan amendment is April 1, 2014. Therefore, DMMA envisions adopting the new methodology without time to even consider comments which can be submitted until March 31 and this could have a significant impact on pharmacies.

Thank you for your consideration and please contact SCPD if you have any questions or comments regarding our observations on the proposed regulation.

cc: Mr. Stephen Groff
Mr. Brian Hartman, Esq.
Governor’s Advisory Council for Exceptional Citizens
Developmental Disabilities Council

17reg893 dmma-medicaid prescription drug reimbursement 3-28-14

a benign tumor, and (b) each patient for whom it renders any care after the individual is diagnosed with cancer or a benign tumor. Compliance by one health care provider with this Section with respect to an individual patient shall not obviate compliance by other health care providers with respect to the same patient.

4.0 Forms Supplied by Department

Forms prepared by the Department for use by health care providers in complying with Section [2 3] shall request all data required by the reporting requirements of the National Cancer Data Base established by the American College of Surgeons. Forms prepared under this section shall also request disclosure of the address at which the patient has lived for the longest period of time, the occupation at which the patient has worked for the longest period of time, and the name and address of the employer at the occupation where the patient has worked for the longest period of time, if such information is available to the health care provider. A health care provider shall make reasonable efforts to obtain all information requested by the form prepared under this Section. However, reasonable efforts by a clinical laboratory shall not include the interviewing of patients to obtain required information.

5.0 Retention of Required Information

A health care provider who is treating a patient who has been diagnosed with cancer or a benign tumor shall ask that patient to fill out a form requesting disclosure of the address at which the patient has lived for the longest period of time in his or her life, the occupation at which the patient has worked for the longest period of time in his or her life, and the name and address of the employer at the occupation where the patient has worked for the longest period of time. The health care provider shall retain the form required by this Section with the patient's medical records pursuant to generally accepted protocol for the retention of patient medical records. The health care provider shall include the information from the form required by this Section with information it submits pursuant to Section [2 3] of these regulations. The Department shall provide a form for use in complying with this Section.

6.0 Deadlines for Submission

A health care provider shall provide the information required by Section [2 3] within 180 days of the initiation of treatment of a patient or diagnosis of that patient with a cancer or benign tumor, whichever is earlier.

7.0 Failure to Submit Required Information

A health care provider that fails to comply with Section 5 shall permit the Department to audit its records and abstract information that should have been provided under Section [5 6]. The health care provider shall reimburse the

Department for the cost of said audit. If the audit does not identify a compliance failure by the health care facility or provider, the cost of such audit shall not be assessed against the facility or provider.

8.0 Voluntary Audit

A health care provider may voluntarily request that an audit be performed if it does not intend to submit the information required by Section [5 6]. The Department shall determine if the request for an audit will be honored. The health care provider shall reimburse the Department for the cost of said audit if the Department honors the request. The Department shall determine whether said costs shall be prepaid, or paid upon completion of the audit.

9.0 Fines

Failure to comply with Section [5 6] of these regulations may result in a \$100 fine against the health care provider that has failed to comply. Each failure to comply shall constitute a separate violation and shall subject the health care provider to a separate \$100 fine.

DIVISION OF SOCIAL SERVICES
Statutory Authority: 31 Delaware Code,
Section 505 (31 Del.C. §505)

ORDER

Nature Of The Proceedings:

Delaware Health and Social Services ("Department") / Division of Social Services initiated proceedings to amend the Title XIX Medicaid State Plan to change drug-pricing methodology, effective January 1, 2003. The Department's proceedings to amend its regulations were initiated pursuant to 29 Delaware Code Section 10114 and its authority as prescribed by 31 Delaware Code Section 512.

The Department published its notice of proposed regulation changes pursuant to 29 Delaware Code Section 10115 in the December 2002 Delaware Register of Regulations, requiring written materials and suggestions from the public concerning the proposed regulations to be produced by December 31, 2002 at which time the Department would receive information, factual evidence and public comment to the said proposed changes to the regulations.

Summary Of Proposed Revisions

Currently, Delaware reimburses pharmaceuticals using the lower of:

- the usual and customary charge to the general public for the product,
- the Average Wholesale Price (AWP) minus 12.9% plus a dispensing fee, or
- a State-specific maximum allowable cost (DMAC) and, in some cases, the federally defined Federal Upper Limit (FUL) prices plus a dispensing fee.

The proposed State Plan Amendment (SPA) changes the AWP methodology as follows:

- Brand name drugs:
 - for traditional chain pharmacies and independent pharmacies: AWP minus 16.32% plus a dispensing fee per prescription
 - for non-traditional pharmacies: AWP minus 24.32% plus a dispensing fee per prescription.
- Generic drugs for all pharmacies: Average of the Average Wholesale Price (AAWP) minus 58% plus a dispensing fee per prescription.

There will be no dispensing fee increase.

The SPA also:

- clarifies terms used in the methodology process by revising the definition of the Delaware Maximum Allowable Cost (DMAC);
- provides definitions of traditional and non-traditional pharmacies; and,
- revises reimbursement limits and exceptions.

Summary of Comments Received with Agency Response and Explanation of Change:

Delaware Developmental Disabilities Council (DDDC), Delaware Healthcare Association (DHA), Governor's Council For Exceptional Citizens (GACEC), National Association of Chain Drug Stores (NACDS), and State Council for Persons with Disabilities (SCPD) submitted comments strongly opposing the Medicaid pharmacy reimbursement rate for the Delaware Medical Assistance Program, effective January 1, 2003. Comments are arranged by subject matter and summarized. Staff analysis of the public comments is provided and given a consolidated response below:

DHA comments:

- No comment period and prior notification.
- Providers did not participate in the change process.
- Recommend delay in the cuts until further discussion and negotiations occur between affected providers.

NACDS comments:

- Question the size of the audit sample and some of the audit methodology and state that Delaware dis-

penses fewer generics as a percentage of total prescriptions than other states.

- The pharmacy dispensing fee remains inadequate.
- Cost utilization must be addressed.

DDDC, GACEC and SCPD provided the following similar observations and concerns:

- Reductions are dramatic. Recommend DSS reconsider the drastic reductions and review other options with pharmacies.
- Discuss other cost-cutting alternatives adopted by other states.
- Limits on physician authorization for a name-brand drug.
- Recommend that DSS solicit the Delaware Health Fund Advisory Committee to determine if "tobacco funds" can be used to offset the proposed cost-cutting approaches in order to reach a compromise with the pharmacies.

DSS Response: In response to comments received, the proposed amendment has been revised and the pharmacy policies and rate plans changed and clarified as follows:

- Brand name drugs:
 - for traditional pharmacies: AWP-14% plus dispensing fee per prescription;
 - for non-traditional pharmacies: AWP-16% plus dispensing fee per prescription.
- Generic drugs:
 - for traditional pharmacies: AWP-14% plus dispensing fee per prescription;
 - for non-traditional pharmacies: AWP-16% plus dispensing fee per prescription.

The dispensing fee will remain at \$3.65.

Findings Of Fact:

The Department finds that the proposed changes as set forth in the December 2002 Register of Regulations should be adopted, as herein, revised.

THEREFORE, IT IS ORDERED, that the proposed regulations of the Medicaid/Medical Assistance Programs to amend the Title XIX Medicaid State Plan related to the reimbursement of pharmaceuticals be adopted, as herein revised, and shall be final effective February 10, 2003.

Vincent P. Meconi, Secretary, DHSS, January 15, 2003



TUESDAY, FEBRUARY 18, 2014

How Medicaid is Squeezing Specialty Pharmacy Profits

An Avalere Health report—*Tracking Gaps in State Specialty Pharmacy Reimbursement*—highlights an interesting question: *Do new state Medicaid acquisition-cost pharmacy reimbursement models adequately compensate specialty pharmacies?*



The problem is easy to describe. State Medicaid programs are rapidly adopting acquisition cost methodologies for pharmacy reimbursement. These new models reduce or eliminate pharmacies' spread profits. Higher Medicaid dispensing fees are benchmarked to retail pharmacies and don't account for additional services provided for specialty drugs.

This situation, however, is hard to fix. Unless it is corrected soon, patients will be the big losers. Avalere implies that states will step up with higher fees. Instead, I suspect that manufacturers will be expected to pick up the tab as specialty pharmacies' spreads get squeezed.

BUTTERING THE BREAD

A pharmacy typically earns the majority of its gross profits from spreads between third-party ingredient reimbursement and net acquisition costs. For specialty drugs, these spreads are about 5% to 10%, or \$150 to \$300 for a \$3,000 brand-name specialty prescription.

As we discuss in Chapter 5 of the *2013–14 Economic Report on Retail, Mail, and Specialty Pharmacies*, state Medicaid programs are rapidly adopting average acquisition cost (AAC) methodologies. Six state Medicaid programs—Alabama, Colorado, Idaho, Iowa, Louisiana, and Oregon—rely on AAC data for pharmacy reimbursement. New York state recently launched its own AAC program.

The introduction of cost-based reimbursement models can benefit retail pharmacies. Spreads vanish (or shrink sharply) when ingredient cost reimbursement approximates actual drug acquisition costs. Compensation for prescription dispensing shifts from a spread-based model to a service-based model.

Consequently, state Medicaid programs have increased per-prescription dispensing fees to \$9 to \$15. Some states using AAC-based reimbursement use tiered dispensing fees based on a pharmacy's annual prescription volume or other factors.

SQUEEZING THE SPREAD

Alas, even the higher dispensing fees won't replace the substantial specialty pharmacy spreads. As the Avalere report rightly notes: "[E]ven states that have implemented an AAC-based reimbursement methodology have not differentiated dispensing fees for specialty/non-specialty drugs or for retail pharmacy/specialty pharmacy."

Specialty drugs in open distribution routinely show up in pharmacy acquisition cost surveys. Examples include such drugs as Avonex, Humira, Enbrel, and Neupogen. Based on the most recent data releases, all four drugs show up in the National Average Drug Acquisition Cost (NADAC) data file and the Alabama Medicaid Agency's AAC list.

Note that the NADAC data are based on 500 to 600 monthly surveys of retail community pharmacies. Specialty pharmacies are excluded from the NADAC surveys.

Here's another complication: State boards of pharmacy lack distinct regulatory requirements that define a "specialty pharmacy." As I note in *The Explosion in Accredited Specialty Pharmacies*, any pharmacy can designate itself a "specialty pharmacy" if its business focus is self-administered specialty pharmaceuticals covered under a patient's pharmacy insurance benefit.

Nonetheless, 66% of Medicaid programs claim to mandate the use of specialty pharmacies for the dispensing of self-administered specialty drugs. (See EMD Serono Survey, 9th edition, page 52.)

I CAN'T BELIEVE IT'S NOT PROFITABLE!

So, who will bear the burden of these reduced reimbursements?

Unfortunately, patients will suffer the most. In addition to basic product dispensing, patients taking specialty medications require services beyond those for traditional drugs. Specialty pharmacies will be caught between declining profit spreads and the patient care costs of higher services. Business survival will translate into reduced services for Medicaid patients.

The Avalere report focuses on blood plasma products, presumably because the report was funded by Grifols (a leading manufacturer of blood plasma products). Perhaps that's why Avalere optimistically writes: "State Medicaid programs may also consider establishing a separate dispensing fee that appropriately accounts for the services associated with the delivery of specialty drugs."

As I see it, it's more likely that manufacturers will be expected (or compelled?) to pick up the tab for those Medicaid patient services, via higher fees for specialty pharmacies. Caveat venditor.