



State of New Jersey

DEPARTMENT OF BANKING AND INSURANCE

OFFICE OF THE COMMISSIONER

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BULLETIN NO. 18-11

TO: ALL HEALTH SERVICE CORPORATIONS, HOSPITAL SERVICE CORPORATIONS, MEDICAL SERVICE CORPORATIONS, HEALTH INSURANCE COMPANIES, HEALTH MAINTENANCE ORGANIZATIONS, ORGANIZED DELIVERY SYSTEMS, PHARMACY BENEFITS MANAGERS AND OTHER INTERESTED PARTIES

FROM: MARLENE CARIDE, COMMISSIONER

**RE: COMPLIANCE WITH N.J.S.A. 17B:27F-4 and 17B:27-46.1
COMPLIANCE WITH AMENDMENTS TO N.J.S.A. 17:48H-1**

N.J.S.A. 17B:27F-4, effective April 10, 2016, requires that all contracts between a pharmacy benefits manager and a contracted pharmacy include a process to appeal, investigate, and resolve disputes regarding multiple source generic drug pricing. The statute specifies that if an appeal of a multiple source generic drug price is denied, the pharmacy benefits manager shall provide the reason for the denial and identify the national drug code of a drug product that is available for purchase by contracted pharmacies in the State from wholesalers registered under N.J.S.A. 24:6B-1 to -13 at a price which is equal to or less than the maximum allowable cost for the appealed drug as determined by the pharmacy benefits manager. The Department adopted regulations effective January 2, 2018 containing the same provision, see N.J.A.C. 11:4-62.4(b)1.

It has come to the attention of the Department that some pharmacy benefit managers do not identify the wholesaler from which the appealing pharmacy can procure the multiple source generic drug at or below the pharmacy benefit manager's maximum allowable cost in their denials of pharmacy appeals of multiple source drug pricing. The Department interprets the statute and its rule as requiring identification of such wholesalers so that the appealing pharmacy can obtain the drug at a price equal to or less than the pharmacy benefit manager's maximum allowable cost. Therefore, pharmacy benefit managers are directed to include in their denials of multiple source drug pricing appeals the name of wholesalers registered under N.J.S.A. 24:6B-1 to -13 from which the appealing pharmacy can obtain the multiple source generic drug at or below the maximum allowable cost determined by the pharmacy benefits manager.

The Department is also reminding health, hospital and medical service corporations, health insurance companies, health maintenance organizations, organized delivery systems and pharmacy

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benefit managers that N.J.S.A. 17B:27-46.1i(a)(4)(a) and related statutes provide that carriers may not require that pharmacy services and prescription drugs be obtained from a mail service pharmacy. Although the Department has allowed carriers to require that specialty drugs be obtained from specialty pharmacies and this may in some circumstances be by mail order only, the Department is concerned that this exception may be being abused through application to drugs that are routinely dispensed by most pharmacies. Therefore, pharmacy benefit managers and carriers are advised that only drugs which meet the requirements of 45 C.F.R. 156.122(e) will be considered specialty drugs which may have limited sources. That regulation requires that either the drug be subject to restricted distribution by the U.S. Food and Drug Administration or the drug requires special handling, provider coordination, or patient education that cannot be provided by a retail pharmacy. If these requirements are not met, the drug cannot be considered a specialty drug and must be covered if obtained at a retail pharmacy.

Lastly, P.L. 2017, c. 383, enacted January 16, 2018, requires that beginning April 16, 2018, pharmaceutical services are considered "limited health care services" under the Organized Delivery System Act ("Act"), N.J.S.A. 17:48H-1 to -35. This means that pharmacy benefit managers, i.e., entities that act on behalf of a carrier to provide, or arrange to provide, pharmaceutical services, which the carrier elects to subcontract for as a separate category of benefits and services apart from its delivery of benefits under its comprehensive benefits plan, must become either certified or licensed as an organized delivery system pursuant to the Act.

Under the Act, as amended, a pharmacy benefit manager must be licensed if it is compensated on a basis which entails the assumption of financial risk and must be certified if it is compensated on a basis which does not entail the assumption of financial risk. Financial risk is defined as exposure to financial loss that is attributable to the liability of an organized delivery system for the payment of claims or other losses arising from covered benefits for treatment or services other than those performed directly by the person or organized delivery system for payment, including a loss sharing arrangement.

The Department has received inquiries from persons and entities affected by the Act regarding their continued operations pending the Department's promulgation of any necessary regulations. Pharmacy benefit managers are advised that they may continue to operate in this State until such time as the Department adopts regulations implementing the Act. In the interim, the Department requests that pharmacy benefit managers submit a Notification of Organized Delivery System Anticipated Application to the Office of Solvency Regulation, which is posted on the Department's website at:

https://www.state.nj.us/dobi/division_insurance/pharmacybenefitsmanagers/index.htm.

Questions about the application process may be addressed to Tim Stroud, 609-292-5350, extension 50070, tim.stroud@dobi.nj.gov.

The Department anticipates proposing any necessary regulations to implement the above in the near future. Interested parties may access the Department's website at <http://www.nj.gov/dobi/legsregs.htm> to determine whether those regulations have been proposed.

9/10/18
Date

MCaride
Marlene Caride
Commissioner

PBM Bulletin jc/bulletins

NEW JERSEY DEPARTMENT OF BANKING and INSURANCE

**NOTIFICATION of ORGANIZED DELIVERY SYSTEM
ANTICIPATED APPLICATION FOR
LICENSURE/EXEMPTION FROM LICENSURE/CERTIFICATION
FOR PHARMACY BENEFIT MANAGERS**

**New Jersey Department of Banking and Insurance
Life and Health Admissions P.O. Box 325, Trenton, NJ 08625-0325**

Anticipated Application: Licensure ____ Certification ____ Exemption from Licensure ____

If plan on seeking exemption, explain basis for proposed exemption:

1. Name of Applicant

2. Physical Address of Applicant

3. Mailing Address
If different from physical address

4. Organizational Information

_____ Corporation _____ Trust _____ LLC
_____ Prof. Corp. _____ Prof. Assoc. _____ Other

5. Provide a brief description of the services the PBM provides in this State:

6. City and State of Incorporation (if appl.) City _____ State _____

Federal Employer Identification number or _____ - _____

Social Security Number _____ - ____ - _____

7. Contact Person _____

8. Phone Number (_____) _____

9. Toll Free Number (_____) _____

10. Fax Number (_____) _____

11. Email Address _____

Certification

I _____ certify that I am authorized to file this certification on behalf of the
(Name and Title)

applicant, the information set forth in this certification is true to the best of information, knowledge and belief, and that the Department of Banking and Insurance may rely on the information set forth above.

Signature of Applicant

Full Legal Name (Type or Print)

Title

Date