



Office of the
Medicaid Inspector
General

DENNIS ROSEN
Medicaid Inspector General

Audit of Claims for Pharmacy Services

Final Audit Report

Audit #: 16-1638

Biologics, Inc.

Provider ID #: [REDACTED]

NPI #: [REDACTED]



**Office of the
Medicaid Inspector
General**

ANDREW M. CUOMO
Governor

DENNIS ROSEN
Medicaid Inspector General

September 20, 2016

[REDACTED]
Biologics, Inc.
120 Weston Oaks Court
Cary, North Carolina 27513-2256

Re: Final Audit Report
Audit #: 16-1638
Provider ID #: [REDACTED]

Dear [REDACTED]

This is the New York State Office of the Medicaid Inspector General's (OMIG) Final Audit Report for Biologics, Inc. (Provider).

In accordance with Sections 30, 31 and 32 of the New York State Public Health Law, and Title 18 of the Official Compilation of the Codes, Rules and Regulations of the State of New York (NYCRR) Parts 504 and 517, OMIG conducted an audit of Medicaid pharmacy claims paid to the Provider from September 6, 2011, through February 26, 2016.

OMIG has attached the sample detail for the paid claims determined to be in error. This Final Audit Report incorporates consideration of any additional documentation and information presented in the Provider's July 20, 2016 response to OMIG's May 20, 2016 Draft Audit Report.

If you have any questions or comments concerning this report, please contact [REDACTED] [REDACTED] Please refer to audit number 16-1638 in all correspondence.

[REDACTED]
Division of Medicaid Audit
Office of the Medicaid Inspector General

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Background, Objective, and Audit Scope

Background

The New York State Department of Health (DOH) is the single state agency responsible for the administration of the Medicaid program. As part of its responsibility as an independent entity within DOH, the Office of the Medicaid Inspector General (OMIG) conducts audits and reviews of various providers of Medicaid reimbursable services, equipment and supplies. These audits and reviews are directed at assessing provider compliance with applicable laws, regulations, rules and policies of the Medicaid program as set forth in New York Public Health Law, New York Social Services Law, the regulations of DOH (Titles 10 and 18 of the New York Codes Rules and Regulations), the regulations of the Education Department (Title 8 of the New York Codes Rules and Regulations), DOH's Medicaid Provider Manuals and *Medicaid Update* publications.

Objective

The objective of this audit was to assess Biologics, Inc.'s (Provider) adherence to applicable laws, regulations, rules and policies governing the New York State Medicaid program and to identify overpayments for drug claims not authorized to be reimbursed pursuant to its provider enrollment.

Audit Scope

The audit covers claims paid by Medicaid from September 6, 2011, through February 26, 2016.

Regulations of General Application

In addition to the regulations cited to support each category of audit findings, the following regulations pertain to all findings:

Regulations state: "By enrolling the provider agrees: (a) to prepare and to maintain contemporaneous records demonstrating its right to receive payment . . . and to keep for a period of six years from the date the care, services or supplies were furnished, all records necessary to disclose the nature and extent of services furnished and all information regarding claims for payment submitted by, or on behalf of, the provider . . . (e) to submit claims for payment only for services actually furnished and which were medically necessary or otherwise authorized under the Social Services Law when furnished and which were provided to eligible persons; (f) to submit claims on officially authorized claim forms in the manner specified by the department in conformance with the standards and procedures for claims submission; . . . (h) that the information provided in relation to any claim for payment shall be true, accurate and complete; and (i) to comply with the rules, regulations and official directives of the department."
18 NYCRR Section 504.3

Regulations state: "Fee-for-service providers. (1) All providers . . . must prepare and maintain contemporaneous records demonstrating their right to receive payment . . . All records necessary to disclose the nature and extent of services furnished and the medical necessity therefor . . . must be kept by the provider for a period of six years from the date the care, services or supplies were furnished or billed, whichever is later. (2) All information regarding claims for payment submitted by or on behalf of the provider is subject to audit for a period of six years from the date the care, services or supplies were furnished or billed, whichever is later, and must be furnished, upon request, to the department . . . for audit and review."

18 NYCRR Section 517.3(b)

Regulations require that bills for medical care, services and supplies contain patient name, case number and date of service; itemization of the volume and specific types of care, services and supplies provided; the unit price and total cost of the care, services and supplies provided; and a dated certification by the provider that the care, services and supplies itemized have been in fact furnished; that the amounts listed are in fact due and owing; that such records as are necessary to disclose fully the extent of care, services and supplies provided to individuals under the New York State Medicaid program will be kept for a period of not less than six years from the date of payment; and that the provider understands that payment and satisfaction of this claim will be from Federal, State and local public funds and that he or she may be prosecuted under applicable Federal and State laws for any false claims, statements or documents, or concealment of a material fact provided.

18 NYCRR Section 540.7(a)(1)-(3) and (8)

Regulations state: "An overpayment includes any amount not authorized to be paid under the medical assistance program, whether paid as the result of inaccurate or improper cost reporting, improper claiming, unacceptable practices, fraud, abuse or mistake."
18 NYCRR Section 518.1(c)

Regulations state: "Vendor payments for medical care and other items of medical assistance shall not be made unless such care or other items of assistance have been furnished on the basis of the appropriate authorization prescribed by the rules of the board and regulations of the department."

18 NYCRR Section 540.1

Regulations state: "The department may require repayment from the person submitting an incorrect or improper claim, or the person causing such claim to be submitted, or the person receiving payment for the claim."

18 NYCRR Section 518.3(a)

Regulations state: "The department may require repayment for inappropriate, improper, unnecessary or excessive care, services or supplies from the person furnishing them, or the person under whose supervision they were furnished, or the person causing them to be furnished...."

18 NYCRR Section 518.3(b)

Regulations state: "Medical care, services or supplies ordered or prescribed will be considered excessive or not medically necessary unless the medical basis and specific need for them are fully and properly documented in the client's medical record."

18 NYCRR Section 518.3(b)

Audit Findings

Submitting Claims for Unauthorized Services

Duties of the provider: (i) to comply with the rules, regulations and official directives of the department.
18 NYCRR Section 504.3(i)

Denial of an application shall preclude the applicant from submitting claims for payment under the medical assistance program either directly, or indirectly through any other person. Any claims submitted by such applicant or such other person and paid by the department shall constitute overpayments.
18 NYCRR Section 504.5(c)

At various times, Biologics Inc. was authorized to dispense Caprelsa (vandetanib), Inklusig (ponatinib), and Tagrisso (osimertinib), to New York Medicaid recipients. Biologics was not approved to provide any other service to New York State Medicaid recipients and received several official directives stating such. (Attachment A).

In 25 instances pertaining to 5 patients, Biologics Inc. submitted claims for dispensing products which were not approved for reimbursement under its terms of enrollment. This resulted in an overpayment of \$204,333.93 (Attachment A).

Repayment Options

In accordance with 18 NYCRR Part 518, which regulates the collection of overpayments, your repayment options are described below.

Option #1: Make a full payment by check or money order within 20 days of the date of the Final Audit Report. The check should be made payable to the **New York State Department of Health** with the audit number included and be sent with the attached remittance advice to:

[REDACTED]
New York State Department of Health
Medicaid Financial Management
GNARESP Corning Tower, Room 2739
File # 16-1638
Albany, New York 12237

Option #2: Enter into a repayment agreement with OMIG. If your repayment terms exceed 90 days from the date of the Final Audit Report, recoveries of amounts due are subject to interest charges at the prime rate plus 2%. OMIG acceptance of the repayment agreement is based on your repaying the Medicaid overpayment as agreed. OMIG will adjust the rate of recovery, or require payment in full, if your unpaid balance is not being repaid as agreed. If you wish to enter into a repayment agreement, please contact the Bureau of Collections Management within 20 days at the following:

New York State
Office of the Medicaid Inspector General
Bureau of Collections Management
800 North Pearl Street
Albany, New York 12204
Phone #: [REDACTED]
Fax #: [REDACTED]

Should you fail to select a payment option above, OMIG, in its discretion, may use any remedy allowed by law to collect the amount due. Pursuant to the State Finance Law §18(5), a collection fee equal to twenty two percent (22%) of the amount due, including interest, may be added to the amount owed. OMIG's remedies may include, without limitation, filing this Final Audit Report as the final administrative determination for purposes of obtaining a judgment lien pursuant to §145-a of the New York State Social Services Law; withholding Medicaid payments otherwise payable to the provider or its affiliates pursuant to 18 NYCRR 518.6; and imposing a sanction, pursuant to 18 NYCRR 515.2, against a provider who fails to reimburse the department for overpayments discovered by this audit.

Hearing Rights

If you choose not to settle this audit through repayment of the actual overpayment, you have the right to challenge these findings by requesting an administrative hearing where OMIG would seek and defend the actual overpayment of \$204,333.93. As allowed by state regulations, you must make your request for a hearing, in writing, within sixty (60) days of the date of this report to:

General Counsel
Office of Counsel
New York State Office of the Medicaid Inspector General
800 North Pearl Street
Albany, NY 12204

Questions regarding the request for a hearing should be directed to Office of Counsel, at [REDACTED]

In accordance with 18 NYCRR 519.18(a), "The issues and documentation considered at the hearing are limited to issues directly relating to the final determination. An appellant may not raise issues regarding the methodology used to determine any rate of payment or fee, nor raise any new matter not considered by the department upon submission of objections to a draft audit or notice of proposed agency action."

If a hearing is held, you may have a person represent you or you may represent yourself. If you choose to be represented by someone other than an attorney, you must supply along with your hearing request a signed authorization permitting that person to represent you at the hearing; you may call witnesses and present documentary evidence on your behalf.

For a full listing of hearing rights please see 18 NYCRR Part 519.

Contact Information



Office Address:

New York State
Office of the Medicaid Inspector General
Division of Medicaid Audit
800 North Pearl Street
Albany, New York 12204

Mission

The mission of the Office of the Medicaid Inspector General is to enhance the integrity of the New York State Medicaid program by preventing and detecting fraudulent, abusive, and wasteful practices within the Medicaid program and recovering improperly expended Medicaid funds while promoting high quality patient care.

Vision

To be the national leader in promoting and protecting the integrity of the Medicaid program.



Office of the
Medicaid Inspector
General

REMITTANCE ADVICE

Biologics, Inc.
120 Weston Oaks Court
Cary, North Carolina 27513-2256

Provider ID #: [REDACTED]

Audit #: 16-1638

Amount Due: \$204,333.93

Audit
Type

- Managed Care
- Fee-for-Service
- Rate

Checklist

1. To ensure proper credit, please enclose this form with your check.
2. Make checks payable to: New York State Department of Health.
3. Record the audit number on your check.
4. Mail the check to:

[REDACTED]
 New York State Department of Health
 Medicaid Financial Management
 GNARESP Corning Tower, Room 2739
 File #16-1638
 Albany, New York 12237

ATTACHMENT A

FINAL DISPOSITION FOR SAMPLED SELECTIONS CHANGED FROM DRAFT TO FINAL AUDIT REPORT

**BIOLOGICS , INC.
 OMIG AUDIT# 16-1638 PROVIDER# [REDACTED]
 AUDIT #16-1638
 AUDIT PERIOD: 09/06/2011 - 02/26/2016**

BRIDGE SCHEDULE

DATE OF SERVICE	FINDING	DRAFT REPORT AMOUNT DISALLOWED	FINAL REPORT AMOUNT DISALLOWED	CHANGE
10/01/2015	Billed Excess Dispensing Limits for Controlled Substance	\$5,578.10	\$0.00	-\$5,578.10
10/15/2015	Billed Excess Dispensing Limits for Controlled Substance	\$5,578.10	\$0.00	-\$5,578.10
10/27/2015	Billed Excess Dispensing Limits for Controlled Substance	\$5,578.10	\$0.00	-\$5,578.10
02/12/2015	Billed Excess Dispensing Limits for Controlled Substance	\$11,155.70	\$0.00	-\$11,155.70
03/23/2015	Billed Excess Dispensing Limits for Controlled Substance	\$2,789.30	\$0.00	-\$2,789.30
04/06/2015	Billed Excess Dispensing Limits for Controlled Substance	\$2,789.30	\$0.00	-\$2,789.30
04/16/2015	Billed Excess Dispensing Limits for Controlled Substance	\$2,789.30	\$0.00	-\$2,789.30
04/29/2015	Billed Excess Dispensing Limits for Controlled Substance	\$2,789.30	\$0.00	-\$2,789.30
05/13/2015	Billed Excess Dispensing Limits for Controlled Substance	\$2,789.30	\$0.00	-\$2,789.30
06/23/2014	Billed Excess Dispensing Limits for Controlled Substance	\$8,167.70	\$8,167.70	\$0.00
07/23/2014	Billed Excess Dispensing Limits for Controlled Substance	\$8,167.70	\$8,167.70	\$0.00
09/02/2014	Billed Excess Dispensing Limits for Controlled Substance	\$8,167.70	\$8,167.70	\$0.00
09/24/2014	Billed Excess Dispensing Limits for Controlled Substance	\$8,739.40	\$8,739.40	\$0.00

ATTACHMENT A

FINAL DISPOSITION FOR SAMPLED SELECTIONS CHANGED FROM DRAFT TO FINAL AUDIT REPORT

BIOLOGICS , INC.
OMIG AUDIT# 16-1638 PROVIDER# [REDACTED]
AUDIT #16-1638
AUDIT PERIOD: 09/06/2011 - 02/26/2016

BRIDGE SCHEDULE

DATE OF SERVICE	FINDING	DRAFT REPORT AMOUNT DISALLOWED	FINAL REPORT AMOUNT DISALLOWED	CHANGE
11/26/2014	Billed Excess Dispensing Limits for Controlled Substance	\$8,739.40	\$8,739.40	\$0.00
12/29/2014	Billed Excess Dispensing Limits for Controlled Substance	\$8,739.40	\$8,739.40	\$0.00
07/24/2015	Billed Excess Dispensing Limits for Controlled Substance	\$12,179.70	\$12,179.70	\$0.00
04/24/2015	Billed Excess Dispensing Limits for Controlled Substance	\$9,132.66	\$9,132.66	\$0.00
05/29/2015	Billed Excess Dispensing Limits for Controlled Substance	\$9,132.66	\$9,132.66	\$0.00
06/29/2015	Billed Excess Dispensing Limits for Controlled Substance	\$9,135.66	\$9,135.66	\$0.00
07/28/2015	Billed Excess Dispensing Limits for Controlled Substance	\$9,135.66	\$9,135.66	\$0.00
08/24/2015	Billed Excess Dispensing Limits for Controlled Substance	\$9,135.66	\$9,135.66	\$0.00
09/22/2015	Billed Excess Dispensing Limits for Controlled Substance	\$9,135.66	\$9,135.66	\$0.00
11/02/2015	Billed Excess Dispensing Limits for Controlled Substance	\$9,546.61	\$9,546.61	\$0.00
11/30/2015	Billed Excess Dispensing Limits for Controlled Substance	\$9,546.61	\$9,546.61	\$0.00
12/29/2015	Billed Excess Dispensing Limits for Controlled Substance	\$9,546.61	\$9,546.61	\$0.00
05/18/2015	Billed Excess Dispensing Limits for Controlled Substance	\$4,406.80	\$4,406.80	\$0.00

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FINAL DISPOSITION FOR SAMPLED SELECTIONS CHANGED FROM DRAFT TO FINAL AUDIT REPORT

BIOLOGICS , INC.
OMIG AUDIT# 16-1638 PROVIDER# [REDACTED]
AUDIT #16-1638
AUDIT PERIOD: 09/06/2011 - 02/26/2016

BRIDGE SCHEDULE

DATE OF SERVICE	FINDING	DRAFT REPORT AMOUNT DISALLOWED	FINAL REPORT AMOUNT DISALLOWED	CHANGE
05/29/2015	Billed Excess Dispensing Limits for Controlled Substance	\$4,406.80	\$4,406.80	\$0.00
06/15/2015	Billed Excess Dispensing Limits for Controlled Substance	\$4,406.80	\$4,406.80	\$0.00
06/29/2015	Billed Excess Dispensing Limits for Controlled Substance	\$4,406.80	\$4,406.80	\$0.00
07/15/2015	Billed Excess Dispensing Limits for Controlled Substance	\$4,406.80	\$4,406.80	\$0.00
07/29/2015	Billed Excess Dispensing Limits for Controlled Substance	\$4,406.80	\$4,406.80	\$0.00
10/19/2015	Billed Excess Dispensing Limits for Controlled Substance	\$10,514.78	\$10,514.78	\$0.00
11/18/2015	Billed Excess Dispensing Limits for Controlled Substance	\$10,514.78	\$10,514.78	\$0.00
12/17/2015	Billed Excess Dispensing Limits for Controlled Substance	\$10,514.78	\$10,514.78	\$0.00
TOTALS		<u>\$246,170.43</u>	<u>\$204,333.93</u>	<u>-\$41,836.50</u>

Note: The adjustments shown above only reflect those that were revised as a result of the provider's response. All other financial adjustments remain the same as shown in the Draft Audit Report.