

Pursuant to the authority vested in the Medicaid Inspector General by Section 32(20) of the Public Health Law, Part 516 of Title 18 (Social Services) of the Official Compilation of Codes, Rules and Regulations of the State of New York is repealed and a new Part 516 is added, to be effective upon publication of a Notice of Adoption in the New York State Register, to read as follows:

Part 516 is repealed and a new Part 516 is adopted to read as follows:

Part 516 Monetary Penalties

Section 516.1 Scope and definitions

Section 516.2 Notice

Section 516.3 Effect and enforcement of the penalty

516.1 Scope and definitions.

(a) Scope. Social Services Law authorizes the imposition of monetary penalties for certain violations of the Medical Assistance (MA) program. This Part shall apply to monetary penalties imposed by the Office of the Medicaid Inspector General (OMIG) pursuant to sections 145-b(4), 363-d, and 364-j(38) of the Social Services Law. Nothing in this Part shall preclude or limit the Department of Health's ability to impose or levy fines or penalties or take any administrative actions under other provisions of this Title.

(b) Definitions. For purposes of sections 145-b(4), 363-d, and 364-j(38) of the Social Services Law, and this Part, the terms defined in Parts 504, 515 and 521 of this Title, except as may be provided for herein, and the following terms apply:

(1) “*Encounter*” means all encounter records, or adjustments to previously submitted records, which the managed care provider or managed long term care plan (MLTCP) has received and processed from provider encounter or claim records of all contracted services rendered to an enrollee of the managed care provider or MLTCP in the current or any preceding month.

(2) “*Failure to grant timely access to records and facilities*” means the failure to produce or make available for review, copying, and inspection requested material, or to provide access to facilities upon reasonable notice by the deadline specified in the written request made by OMIG, the department, or the deputy attorney general for Medicaid Fraud Control.

(3) “*Item or service*” means all medical care, services or supplies claimed to have been provided or furnished to a recipient of the MA program and which is listed in an itemized claim for payment or encounter.

(4) “*Office of the Medicaid Inspector General*” or “*OMIG*” means the independent office within the department established pursuant to Title 3 of Article 1 of the New York State Public Health Law.

(5) “*Person*” is as defined in Part 504 of this Title, except for monetary penalties imposed pursuant to section 145-b(4) of the Social Services Law. For purposes of section 145-b(4) of the Social Services Law “person” is as defined in that section.

(6) “*Standards of generally accepted practice*” means the degree of knowledge, skill and diligence possessed by, or required of, the average member of the

profession or specialty which is practiced. Standards of generally accepted practice also include those practices which are accepted as effective and appropriate by the medical and scientific community of this State.

(7) “*Standards of the MA program*” include but are not limited to the standards set forth in the rules, regulations, and official directives of the department.

(8) “*Substantial number of cases*” means five percent or more of those claims, encounters, or cases identified in any audit, investigation or review, or any sample of cases which were the subject of an audit or otherwise reviewed by the department and for which claims were submitted by a person for payment under the MA program.

516.2 Notice.

(a) Notice of proposed agency action.

(1) When OMIG proposes to impose a monetary penalty under this Part, OMIG must first send the person a written notice of proposed agency action. Such notice must be mailed to the person’s designated payment address, designated correspondence address, or last known address.

(2) The notice of proposed agency action must contain:

(i) the alleged violation(s);

(ii) facts which support the conclusion that a violation has occurred;

(iii) the amount of the proposed monetary penalty;

(iv) the legal authority for the penalty;

(v) the opportunity for the person to submit documentation or written arguments objecting to the proposed action within 30 calendar days of receipt of the notice of proposed agency action. The objections must be in writing and include a written statement detailing the specific items in the notice of proposed agency action to which the person objects; and

(vi) a statement that the failure to object within the time provided may result in the adoption of the proposed penalties as the final penalties and that, pursuant to section 519.18 of this Title, the issues to be addressed at an administrative hearing will be limited to those matters contained in any objection to the proposed action.

(3) Any documentation or written arguments submitted by the person objecting to the notice of proposed agency action must be mailed to OMIG, at the address specified in the notice of proposed agency action, within 30 calendar days of receipt of the notice of proposed agency action which will be presumed, in the absence of evidence to the contrary, to be five calendar days after the date on the notice of proposed agency action.

(4) For good cause shown, OMIG may, in its discretion, extend the 30-calendar day period to respond to the notice of proposed agency action.

(b) Notice of agency action.

(1) If, after its review, OMIG determines to impose a monetary penalty, it must send a written notice of agency action advising the person of the final

determination at least 20 days before the action becomes effective. In preparing the notice of agency action, OMIG must consider the person's objections, any supporting documents and materials, if any, submitted in response to the notice of proposed agency action. Such notice must be either mailed to the person's designated payment address, designated correspondence address, or last known address.

(2) The notice of agency action must contain:

- (i) the alleged violation(s);
- (ii) facts which support the conclusion that a violation has occurred;
- (iii) the amount of the monetary penalty;
- (iv) the legal authority for the penalty;
- (v) the effective date of the penalty; and
- (vi) the right of the person to appeal the determination and of the requirements and procedures for requesting an administrative hearing.

(3) Where a person timely requests a hearing to review the imposition of a penalty, such hearing must be conducted pursuant to the provisions of Part 519 of this Title.

516.3 Effect and enforcement of the penalty.

(a) General.

(1) The imposition of a penalty under this Part does not preclude the recovery of an overpayment or the imposition of any other penalty authorized by Federal or State law or regulation.

(2) Notwithstanding the imposition of any penalty under this Part, the department may also sanction a person pursuant to Part 515 of this Title.

(b) Collection of penalties.

(1) When the person against whom a penalty was imposed does not pay the penalty, the department may recover the amount of the penalty in the same manner as the recovery of an overpayment as set forth in Part 518 of this Title or by any other means authorized by statute, or the rules and regulations of the department.

(2) Interest will accrue on the amount of the penalty commencing on the 90th day after the date of OMIG's notice of agency action. Interest will accrue at the rate set forth in section 518.4(c) of this Title. Interest may be waived in whole or in part when OMIG determines the imposition of interest would effect an unjust result, would unduly burden the provider or would substantially delay the prompt and efficient resolution of an outstanding audit or investigation.

REGULATORY IMPACT STATEMENT

Statutory Authority

The Office of the Medicaid Inspector General (OMIG) is an independent office within the Department of Health (DOH) responsible for the prevention, detection and investigation of fraud and abuse in New York State's Medical Assistance (Medicaid) program pursuant to New York State Public Health Law § 31.

Public Health Law § 32 sets forth the functions, duties and responsibilities of OMIG, and specifically authorizes OMIG to "implement and amend, as needed, rules and regulations related to the prevention, detection, investigation and referral of fraud and abuse within the medical assistance program and the recovery of improperly expended medical assistance program funds." PHL § 32(20). New York State Social Services Law (SOS) §§ 145-b(4), 363-d and 364-j(38) authorizes the imposition of monetary penalties for certain violations of Medicaid program rules and requirements.

Legislative Objectives

The legislative objective is to protect the fiscal integrity of the Medicaid program and promote provider compliance with Medicaid program laws, rules and requirements. The purpose of this rulemaking is to update State regulations governing the imposition of monetary penalties by OMIG and to ensure that individuals and entities against whom such monetary penalties are imposed have the due process protections granted under the statute (SOS § 145-b(4) and SOS § 363-d). In April 2020, the legislature amended SOS § 145-b(4) to authorize the imposition of monetary penalties in cases where a person fails to grant timely access to records and facilities; fails to report, return and

explain overpayments within sixty (60) days of identification; and arranges or contracts, by employment or otherwise, with an individual or entity that has been excluded or suspended from participation in the Medicaid program. In addition, SOS § 363-d was amended to authorize the imposition of a monetary penalty in cases where a required provider fails to adopt and implement an effective compliance program. Finally, SOS § 364-j(38) was amended to authorize the imposition of a monetary penalty in cases where a managed care provider, which includes a managed long term care plan submits a cost report to DOH that contains a misstatement of fact. In each of these amended sections, the statute requires that the individual or entity be given notice and opportunity to be heard.

Needs and Benefits

This rulemaking is required before the State can implement provisions of the SFY 2020-2021 enacted budget. Social Services Law sections 145-b(4), 363-d and 364-j(38) each require that the individual or entity against whom monetary penalties are to be imposed be given notice and an opportunity to be heard in accordance with Section 22 of the Social Services Law. Pursuant to 18 NYCRR Part 519 a person is entitled to an administrative hearing where the department imposes a monetary penalty under 18 NYCRR Part 516. This rulemaking repeals and replaces Part 516 to incorporate the new monetary penalties added by statute and outlines the procedures for imposing such penalties to ensure that the due process protections contemplated by the statute are effectuated. It also removes sections of the prior rule which unnecessarily duplicated or paraphrased the authorizing statute. For example, section 516.2 formerly specified the amounts of the monetary penalties which could be imposed and section 516.3 set forth

the factors the department must consider in determining the amount of the penalty. In both cases, the regulations mirrored language found in Social Services Law 145-b(4). This rulemaking also protects the integrity of the State's Medicaid program by deterring fraud, waste and abuse.

Costs

Costs to Regulated Parties

As a result of this rulemaking, regulated parties are not expected to incur additional costs for continuing compliance. The penalties are authorized and outlined in Social Services Law sections 145-b(4), 363-d and 364-j(38) for violations of existing Medicaid program requirements. Therefore, any penalties imposed would be pursuant to the statute, not this rulemaking. This rulemaking is necessary to implement the statutory requirement that notice and an opportunity to be heard be given to persons against whom monetary penalties are imposed.

Costs to State Government and the State Agency

State government and OMIG are not expected to incur any additional costs as a result of this rulemaking. Agency personnel will continue to conduct audits, investigations and reviews of individuals and entities participating in the Medicaid program which may now result in the imposition of monetary penalties.

Costs to Local Government

There will be no additional costs to local government as a result of this rulemaking. However, since some units of local government participate as providers in

the Medicaid program they would be subject to the same rules and requirements as any other enrolled Medicaid provider.

Local Government Mandates

The proposed rulemaking does not impose any new program, services, duties or responsibilities upon any county, city, town, village, school district, fire district, or other special district in general.

Paperwork

No additional requirements will be imposed upon regulated parties under the proposed regulation.

Duplication

There are no duplicative or conflicting rules identified.

Alternatives

There were no significant alternatives to be considered.

Federal Standards

The proposed regulation does not exceed any minimum standards of the federal government.

Compliance Schedule

The proposed regulation will take effect upon a Notice of Adoption in the New York State Register. Monetary penalties imposed pursuant to Social Services Law section 363-d, consistent with statute, may only be imposed for compliance program

reviews with calendar years beginning on or after January 1, 2021. Regulated parties should already be complying with the underlying requirements for which penalties may be imposed under this rulemaking.

Agency Contact

Michael T. D’Allaird, Esq.

Office of the Medicaid Inspector General

800 North Pearl Street, 2nd Floor

Albany, New York 12204

(518) 408-5803

rulemaking@omig.ny.gov

**STATEMENT IN LIEU OF REGULATORY FLEXIBILITY ANALYSIS FOR SMALL
BUSINESSES AND LOCAL GOVERNMENTS**

No regulatory flexibility analysis for small businesses and local governments is required pursuant to section 202-b(3)(a) of the State Administrative Procedures Act. The proposed regulation applies to all persons participating in the Medicaid program or providing services to Medicaid beneficiaries, including managed care plans, and does not impose new requirements, but rather outlines the procedures under which monetary penalties, as outlined in statute, will be imposed and the right of all persons subject to such penalties to receive notice and an opportunity to be heard in an administrative hearing before the department. The proposed rulemaking does not impose an adverse economic impact on small businesses or local governments, and it does not impose additional reporting, record keeping, or other compliance requirements on small businesses or local governments that do not already exist elsewhere in law or regulation.

STATEMENT IN LIEU OF RURAL AREA FLEXIBILITY ANALYSIS

No rural area flexibility analysis is required pursuant to section 202-bb(4)(a) of the State Administrative Procedures Act. The proposed regulation applies to all persons participating in the Medicaid program or providing services to Medicaid beneficiaries, including managed care plans, and does not impose new requirements, but rather outlines the procedures under which monetary penalties, as outlined in statute, will be imposed and the rights of all persons subject to such penalties to notice and an opportunity to be heard in an administrative hearing before the department. The proposed rulemaking does not impose an adverse impact on rural areas and does not impose reporting, record keeping, or other compliance requirements on public or private entities that do not already exist elsewhere in law or regulation.

STATEMENT IN LIEU OF JOB IMPACT STATEMENT

A job impact statement for this rulemaking is not required pursuant to section 201-a(2)(a) of the State Administrative Procedures Act. It is apparent from the nature and purpose of the proposed regulations that they will not have a substantial adverse impact on jobs and/or employment opportunities. The proposed rulemaking does not impose additional requirements on regulated parties. Statutes authorize the imposition of penalties in cases where individuals or entities fail to meet requirements that exist elsewhere in law and regulation. This rulemaking does not impose additional penalties or burdens on regulated parties, beyond those authorized by the underlying statutes. Rather, this rulemaking further defines specific terms in the statutes and sets forth the procedures for imposing penalties and the due process afforded to individuals or entities subject to such penalties. It is apparent that the definitions, notice and appeal procedures set forth in this proposed rulemaking will not have a substantial adverse impact on jobs and/or employment opportunities.

ASSESSMENT OF PUBLIC COMMENTS

The New York State Office of the Medicaid Inspector General (“OMIG”) received public comments in response to the proposed rulemaking amending Part 516 of Title 18 of the NYCRR relating to monetary penalties. The comments and OMIG’s responses are summarized below.

Comment: The definition of “Substantial Number of Cases” establishing a five percent threshold of cases, claims or encounters broadens the definition. One commenter suggested it be revised to a twenty-five percent threshold.

Response: The addition of “claims or encounters” clarifies the definition but does not significantly broaden the definition. The Department has determined that the five percent threshold is necessary to ensure program integrity. No changes were made to the regulation in response to this comment.

Comment: OMIG received comments seeking clarification of the terms “Reasonable Notice” and “Deadline” as used in the proposed regulation.

Response: “Reasonable Notice” is defined in Social Services Law § 145-b(4)(a)(i)(D)(ii). OMIG will specify the deadline in its written “Reasonable Notice” to providers. No changes were made to the regulation in response to this comment.

Comment: The regulation includes “rules” and “official directives” in the definition of “Standards of the MA Program,” which are not defined, and in so doing, broadens the scope of the regulation.

Response: Current regulations already make it clear that providers must “comply with the rules, regulations and official directives of the department” (see e.g., 18 NYCRR 504.3). Additionally, the definition of “Standards of the MA program” in the prior version of 18 NYCRR 516.1 did not limit standards to regulations of the department.

Comment: The proposed regulation removes provisions governing the determination of the amount of the monetary penalties.

Response: OMIG will take into consideration all the factors required by Social Services Law § 145-b(4)(b)(i)-(v) when determining the amount of any monetary penalty to be imposed under that section. No changes were made to the regulation in response to this comment.

Comment: OMIG enforcement should demonstrate a reasonable approach towards monetary penalties for provider and plan compliance programs, and articulate considerations that it will follow in determining the amount of monetary penalties.

Response: OMIG will take into consideration all the factors required by Social Services Law § 145-b(4)(b)(i)-(v) when determining the amount of any monetary penalty to be imposed. No changes were made to the regulation in response to this comment.