DEPARTMENT OF HEALTH AND SOCIAL SERVICES

DIVISION OF MEDICAID AND MEDICAL ASSISTANCE

Statutory Authority: 31 Delaware Code, Section 512 (31 **Del.C.** §512)

FINAL

ORDER

Medicaid Provider Screening Requirements and Enrollment Fee and Program Integrity

NATURE OF THE PROCEEDINGS:

Delaware Health and Social Services ("Department") / Division of Medicaid and Medical Assistance (DMMA) initiated proceedings to amend existing provisions in the Delaware Medical Assistance Program (DMAP) Manual specifically, the General Policy Provider Manual regarding *Medicaid Provider Screening Requirements and Provider Enrollment Fee and Program Integrity*. 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 September 2013 Delaware *Register of Regulations*, requiring written materials and suggestions from the public concerning the proposed regulations to be produced by September 30, 2013 at which time the Department would receive information, factual evidence and public comment to the said proposed changes to the regulations.

SUMMARY OF PROPOSAL

Statutory Authority

- Patient Protection and Affordable Care Act (Pub. L. No. 111-148 as amended by the Health Care and Education Reconciliation Act of 2010 (Pub. L. No. 111-152)), together known as the Affordable Care Act. Specifically, Section 6401, *Provider Screening and Other Enrollment Requirements Under Medicare, Medicaid, and CHIP*; and Section 6501, *Termination of Provider Participation Under Medicaid If Terminated Under Medicare or Other State Plan*
- 42 CFR Part 455 Subpart E

Background

Section 6401

Section 6401(a) of the Affordable Care Act, as amended by section 10603 of the Affordable Care Act, establishes procedures under which screening is conducted with respect to providers of medical or other items or services and suppliers under Medicare, Medicaid, and Children's Health Insurance Program (CHIP). Section 1866(j)(2)(B) of the Act requires the Secretary of the U.S. Department of Health and Human Services to determine the level of screening to be conducted according to the risk of fraud, waste, and abuse with respect to the category of provider or supplier. Section 1866(j)(2)(C) of the Act requires the Secretary to impose a fee on each institutional provider of medical or other items or services or supplier, to be used by the Secretary for program integrity efforts. Section 6401(b) of the Affordable Care Act includes requirements for States to comply with the process of screening providers and suppliers and imposing temporary enrollment moratoria for the Medicaid program as established by the Secretary. The Centers for Medicare and Medicaid Services (CMS) implemented these requirements with Federal regulations at 42 CFR Part 455 Subpart E. These regulations were published in the Federal Register, Volume 76, February 2, 2011, and were effective March 25, 2011.

Section 6501

Section 6501 of the Affordable Care Act (ACA) amends section 1902(a)(39) of the Social Security Act (the Act) and requires State Medicaid agencies to terminate the participation of any individual or entity if such individual or entity is terminated under Medicare or any other State Medicaid plan. In final implementing regulations at 42 CFR §455.101, CMS generally defined "termination" as occurring when a State Medicaid program, CHIP, or the Medicare program has taken action to revoke a Medicaid or CHIP provider's or Medicare provider or supplier's billing privileges and the provider has exhausted all applicable appeal rights or the timeline for appeal has expired. CMS also indicated in final implementing regulations at 42 CFR §455.101, that the requirement to terminate under section 6501 of the ACA only applies in cases where providers, suppliers or eligible professionals have been terminated or had their billing privileges revoked "for cause." Section 6501 builds upon section 6401(b)(2) which requires that CMS establish a process to make provider termination information available to State Medicaid programs.

Summary of Proposal

To receive reimbursement under the Delaware Medical Assistance Program (DMAP), a provider must be eligible and actively enrolled. The provider is enrolled when certain conditions are met and are applicable to the provider type.

Section 6401 and Section 6501 of the Affordable Care Act mandate provider screening and enrollment requirements that State Medicaid agencies must implement. Please refer to *42 CFR 455 Subpart E – Provider Screening and Enrollment* for the complete set of rules and regulations. Delaware Medicaid must implement these requirements to comply with Federal law.

To become compliant with the ACA-mandated provider screening and enrollment requirements, the Division of Medicaid and Medical Assistance (DMMA) is updating the Program Integrity provisions of the General Policy Provider Manual at Section 1.39 to include the following provisions:

- An enrollment fee for institutional providers as described in 42 CFR §455.460 (section 6401(a));
- Compliance in the event that CMS imposes a temporary enrollment moratoria as described in 42 CFR §455.470 (section 6401(b));
- Termination of provider participation in Medicaid and CHIP upon termination from Medicare or another State's Medicaid program or CHIP on or after January 1, 2011 as described in 42 CFR §455.416 (section 6501); and,
- Screening of providers in accordance with 42 CFR 455.400 et seq. at enrollment, reenrollment and revalidation (section 6401).

Fiscal Impact Statement

These revisions impose no increase in cost on the General Fund.

The costs for system changes are already budgeted in the General Fund.

There will be additional costs for some providers associated with the enrollment/revalidation fee.

SUMMARY OF COMMENTS RECEIVED WITH AGENCY RESPONSE AND EXPLANATION OF CHANGE(S)

The Governor's Advisory Council for Exceptional Citizens (GACEC) and the State Council for Persons with Disabilities (SCPD) offered the following observations and recommendations summarized below. The Division of Medicaid and Medical Assistance (DMMA) has considered each comment and responds as follows.

The Governor's Advisory Council for Exceptional Citizens (GACEC) and the State Council for Persons with Disabilities (SCPD) have reviewed the Department of Health and Social Services/Division of Medicaid and Medical Assistance's (DMMA) proposal to adopt regulations implementing §§6401 and 6501 of the Affordable Care Act. In a nutshell, CMS adopted regulations in 2011 which: 1) require states to adopt certain screening and enrollment standards for Medicaid providers; 2) collect an enrollment fee for institutional providers; 3) authorize a temporary Medicaid provider enrollment moratorium when directed by CMS; 4) terminate provider participation in Medicaid and CHIP if another state has terminated the provider's participation on or after January 1, 2011; and 5) adopt provider screening standards at enrollment, reenrollment and revalidation. The proposed regulation was published as 17 DE Reg. 282 in the September 1, 2013 issue of the *Register of Regulations*. Given time constraints, we have not conducted an exhaustive comparison of the proposed regulation to extensive federal statutory, regulatory, and subregulatory ACA standards. However, we did identify two (2) areas of concern.

First, §§1.39.2.4 and 1.39.2.5 authorize providers terminated from program participation to invoke full appeal rights compiled in the General Policy Provider Manual. In contrast, the attached CMS Bulletin (CPI-B 11-05) contains the following limitation on provider appeal rights:

...When subsequent States terminate based on that initial termination, the scope of their appeals should only review whether the provider was, in fact, terminated by the initiating program. The subsequent appeals process should not review the underlying reasons for the initiating termination. The appeal process in subsequent States does not provide a new forum in which to litigate the basis of termination by another State Medicaid program, Medicare, or CHIP.

DMMA may wish to incorporate this limitation into §1.39.2.5.

Agency Response: DMMA appreciates your comment and has considered your recommendation. The change to proposed §1.39.2.5 to incorporate this limitation is indicated by bracketed, bold type on the final order regulation.

Second, §1.39.2.4 recites that DMMA will check federal databases monthly and "will terminate providers and disclosed entities or individuals who do not meet ACA screening guidelines." This is a "no-exceptions" standard. In contrast, the attached CMS Bulletin (CPI-B 11-05) clarifies that termination is not the invariable result of identification of termination of a provider by another state:

Q. Are there any exceptions to the requirement to terminate a provider that was terminated by Medicare or another State Medicaid program or CHIP?

A. Yes. The statute provides for the same limitations on termination that apply to exclusion under §§1128(c)(3)(B) and 1128(d)(3)(B) of the Social Security Act. Thus, a State may request a waiver of the requirement to terminate a particular provider's participation. State agencies may submit such waiver requests to their respective CMS Regional Offices.

DMMA may wish to consider the following amendment to the last sentence in §1.39.2.4:

DMAP will terminate providers and disclosed entities or individuals who do not meet ACA screening guidelines unless DMAP, in its sole discretion, solicits and secures a waiver from CMS.

Agency Response: DMMA appreciates your comment and has considered your recommendation. The change to proposed §1.39.2.4 regarding exceptions to the requirement to terminate a provider is indicated by bracketed, bold type on the final order regulation.

FINDINGS OF FACT:

The Department finds that the proposed changes as set forth in the September 2013 *Register of Regulations* should be adopted.

THEREFORE, IT IS ORDERED, that the proposed regulation to amend the Delaware Medical Assistance Program (DMAP) Manual specifically, the General Policy Provider Manual regarding *Medicaid Provider Screening Requirements and Provider Enrollment Fee and Program Integrity* is adopted and shall be final effective November 10, 2013.

Rita M. Landgraf, Secretary, DHSS

DMMA FINAL ORDER REGULATION #13-42
REVISION:

1.39.2 Provider Screening and Enrollment

Sections 6401 and 6501 of the Affordable Care Act require States to incorporate additional program integrity provisions within Medicaid and the Children's Health Insurance Program to prevent fraud, waste and abuse. The enhanced provisions include enrollment fees, additional provider screening requirements, temporary provider enrollment moratoria, and provider termination.

1.39.2.1 Provider Enrollment Fee

Effective, March 30, 2010, Section 6401(a) of the Affordable Care Act (ACA) requires states to impose a fee on institutional providers for program integrity efforts. The fee is required at initial enrollment and reenrollment. The enrollment fee amount is established by the Centers for Medicare and Medicaid Services (CMS) and updated annually. The Delaware Medical Assistance Program (DMAP) will begin collection of fees in August of 2013. Institutional providers who have paid the enrollment fee to a Medicare contractor or another State's Medicaid program or Children's Health Insurance Program (CHIP) within the last 365 days are not required to pay an additional enrollment fee to the DMAP. The enrollment fee may also be waived for providers who present proof of hardship exception from CMS.

1.39.2.2 Provider Screening and Enrollment Requirements

The Affordable Care Act (ACA) requires states to perform enhanced screening of providers at initial enrollment, re-enrollment, establishment of a new location, change of location, and revalidation. Providers will also need to complete an annual online disclosure statement identifying persons with 5% or more ownership, controlling interest, and all managing employees. Ordering and referring providers are required to enroll with DMAP in a limited capacity and are subject to the new provider screening initiatives. The ACA requires DMAP to deny or terminate enrollment of any providers, disclosed entities, or individuals who do not meet ACA screening guidelines.

1.39.2.2.1 Provider Risk Categories

Based on the potential for fraud, waste, and abuse, CMS has assessed the various Medicare provider types and assigned risk categories. DMAP will assign a risk category in accordance with CMS guidelines for non-Medicare providers. Provider screening requirements vary depending on ACA-defined risk categories. The risk categories are "limited", "moderate", and "high". Providers falling within two risk levels will be assigned the higher risk category. DMAP reserves the right to modify provider risk levels as it pertains to encumbrances, adverse actions, sanctions, terminations and suspensions.

Limited Risk Level- All providers and disclosure-identified individuals must verify Social Security number, licensure status, taxpayer identification number, and National Provider Identifier. Various databases will be checked for sanctions, exclusions, terminations, and encumbrances. Limited risk level providers include but are not limited to the following as identified by CMS:

- Physicians
- Non physician practitioners
- Medical groups or clinics
- Hospitals
- Ambulatory Surgical Centers (ACSs)
- Early Stage Renal Disease (ESRD) facilities
- Federally Qualified Health Centers (FQHCs)
- Skilled Nursing Facilities (SNFs)

Moderate Risk Level- Moderate risk providers are subject to unannounced pre-enrollment and post-enrollment site visits. Moderate risk providers and disclosure-identified individuals must verify Social Security number, licensure status,

taxpayer identification number, and National Provider Identifier. Various databases will be checked for sanctions, exclusions, terminations, and encumbrances. Moderate risk level providers include but are not limited to the following as identified by CMS:

- Ambulance providers
- Community Mental Health Centers
- CORF - Comprehensive Outpatient Rehabilitation Facilities
- Revalidating Durable Medical Equipment (DME) suppliers
- Revalidating Home Health Agencies (HHA)
- Hospice organizations
- Laboratories - independently owned

High Risk Level- High risk providers and disclosure-identified persons with 5% or more ownership are required to comply with a fingerprint-based background check and unannounced pre-enrollment and post enrollment site visits. High risk providers and disclosure-identified persons must verify Social Security number, licensure status, taxpayer identification number, and National Provider Identifier. Various databases as directed by CMS will be checked for sanctions, exclusions, terminations, and encumbrances. High risk level providers include but are not limited to the following as identified by CMS:

- Durable Medical Equipment suppliers (newly enrolling)
- Home Health Agencies (newly enrolling)

1.39.2.2.2 Ordering, Referring and Prescribing Providers (ORPs)

Physicians and non-physician practitioners whose sole interaction with clients is limited to ordering, referring, or prescribing items and/or services, are required to enroll with DMAP in a limited capacity for purposes of identifying the providers who write the orders, referrals and prescriptions. Providers who are members of Delaware's risk-based managed care organizations are exempt from this requirement. Failure to enroll with DMAP will result in the denial of claims for items ordered, referred, or prescribed for Medicaid beneficiaries by an ORP.

1.39.2.3 Temporary Provider Enrollment Moratoria

The ACA requires States to comply with a temporary provider enrollment moratorium when directed by the federal Secretary of Health and Human Services to combat fraud, waste, and abuse. States may also implement restrictions on new enrollment for provider types that are identified as high risk for fraud, waste, and abuse.

1.39.2.4 Provider Termination

Section 6501 of the ACA mandates that States terminate enrollment of providers who have been terminated from Medicare or another State's Medicaid or CHIP program. On a monthly basis, DMAP will screen all enrolled providers through various federal databases for sanctions, exclusions, and terminations. All individuals and entities identified through annual disclosure statements are also subject to these screenings. DMAP will terminate providers and disclosed entities or individuals who do not meet ACA screening guidelines **[unless DMAP, in its sole discretion, opts to request a waiver from CMS]**.

1.39.2.5 Provider Appeal Rights

[~~Providers may appeal denial and termination decisions as a result of ACA provider screening and enrollment requirements.~~ Denial and termination decisions following provider screening and enrollment procedures are appealable; however, the scope of the appeal is limited to whether the provider was terminated by Medicare or the initiating state Medicaid or CHIP program. The appeal does not provide an opportunity for the provider to contest the basis of the termination by Medicare or other state's Medicaid or CHIP program.] Refer to Section 6.0 Appendix A in the General Policy Provider Manual for information regarding provider appeals.

17 DE Reg. 519 (11/01/13) (Final)