

**Maryland General Assembly
Department of Legislative Services**

**Proposed Regulations
Department of Health and Mental Hygiene
(DLS Control No. 15-087)**

Overview and Legal and Fiscal Impact

The regulations establish, among other requirements, a requirement that certain State-regulated insurers, nonprofit health service plans, health maintenance organizations, and pharmacy benefit managers establish an electronic process to allow a prescriber to override a step therapy or fail-first protocol for pharmaceutical preauthorization requests. The regulations also modify other provisions relating to the preauthorization of health care services.

The regulations present no legal issue of concern.

There is no fiscal impact on State or local agencies beyond that already assumed in the fiscal and policy note for Chapters 316 and 317 of 2014.

Regulations of COMAR Affected

Department of Health and Mental Hygiene:

Maryland Health Care Commission: Benchmarks for Preauthorization of Health Care Services: COMAR 10.25.17.02, .03, .04, and .05

Legal Analysis

Background

Most major purchasers of prescription drugs, including commercial insurers and the pharmacy benefits managers (PBM) with which they contract, utilize step therapy or fail-first protocols to control costs. These measures shift patients to alternative prescription drugs, requiring an individual to try a preferred drug (usually a less costly generic) before progressing to a new drug based on the failure of the first medication to provide symptomatic relief or cure.

Chapters 316 and 317 of 2014 established requirements for step therapy or fail-first protocols imposed by health insurance carriers, including carriers that provide prescription coverage through a PBM. A step therapy or fail-first protocol may not be imposed if the step therapy drug has not been approved by the U.S. Food and Drug Administration (FDA) for the medical condition being treated (*i.e.*, off-label use) or a prescriber provides supporting medical information to the carrier or PBM that a prescription drug covered by the carrier or PBM (1) was ordered for the insured or enrollee within the past 180 days and (2) based on the professional judgment of the prescriber, was effective in treating the insured or enrollee.

The legislation also required the Maryland Health Care Commission (MHCC) to work with payors and providers to attain benchmarks for overriding a payor's step therapy or fail-first protocol. By July 1, 2015, each payor that requires a step therapy or fail-first protocol must establish a process for a provider to override the protocol.

Summary of Regulations

Benchmarks Relating to Step Therapy, Fail-First Protocols, and Preauthorization of Health Care Services

The regulations require certain State-regulated payors of health care services (insurers, nonprofit health service plans, health maintenance organizations, and pharmacy benefit managers) to establish a process to allow a prescriber to override a step therapy or fail-first protocol under certain circumstances. By July 1, 2015, a payor that requires a step therapy or fail-first protocol must establish and maintain an online process to allow a prescriber to override the step therapy or fail-first protocol if the step therapy drug has not been approved by the FDA for the medical condition treated or a prescriber provides "supporting medical information" to the payor that a prescription drug covered by the payor was ordered by the prescriber for the insured or enrollee within the past 180 days and, based on the professional judgment of the prescriber, was effective in treating the insured's or enrollee's disease or medical condition.

Under the regulations, "supporting medical information" is defined to mean a paid claim from a payor that requires a step therapy or fail-first protocol for an insured or an enrollee, a pharmacy record that documents that a prescription has been filled and delivered to an insured or enrollee, or other information mutually agreed to that constitutes sufficient supporting medical information by an insured's or enrollee's prescriber and a payor that requires a step therapy or fail-first protocol.

By July 1, 2015, a payor must also provide notice to prescribers regarding the availability of its online process and information to insureds or enrollees on the availability of the step therapy or fail-first protocol within its network.

The regulations also update provisions that require payors to meet certain benchmarks relating to preauthorization requests for health care services. A payor that becomes authorized to provide benefits or services within the State after October 1, 2012, must not only meet each benchmark within three months of the payor's offering of services, but also maintain the processes or actions required by each benchmark.

Reporting Requirements

The regulations require a payor that requires a step therapy or fail-first protocol to report to MHCC, by August 1, 2015, on its attainment of the benchmark relating to step therapy and fail-first protocols described above. The regulations also specify that a payor that becomes authorized to provide benefits or services within the State after October 1, 2012, must report to MHCC on its attainment of specified benchmarks relating to the preauthorization of health care services within three months of the payor's offering of services or benefits in the State. A payor must demonstrate continued compliance with the benchmarks if requested by MHCC.

Waiver of Benchmark Requirement

The regulations modify provisions authorizing a payor to request that MHCC issue a waiver from the benchmarks relating to preauthorization of health care services. The amendments change the length of time a waiver is valid from one to two years and require payors to submit a renewal of their waiver request 30 days prior to its expiration. The regulations also modify the waiver provisions to provide for waiver requests for the benchmark relating to step therapy and fail-first protocols.

Legal Issue

The regulations present no legal issue of concern.

Statutory Authority and Legislative Intent

MHCC cites §§ 19-101 and 19-108.2 of the Health – General Article as authority for the regulations. Section 19-101 states that the term “Commission” means the Maryland Health Care Commission in provisions of law governing the regulation of health care planning and systems.

Section 19-108.2 of the Health – General Article generally establishes benchmarks for preauthorization of health care services. More specifically, § 19-108.2(a) defines the term “payor” to mean an insurer, nonprofit health services plan, or health maintenance organization that provides certain benefits or a pharmacy benefits manager that is registered with the Maryland Insurance Commissioner. Section 19-108.2(c) specifies, among other requirements, that each payor establish an online preauthorization system to approve electronic preauthorization requests for pharmaceutical and health care services in a specified manner. Section 19-108.2(c) also requires each payor that requires a step therapy or fail-first protocol to establish, by July 1, 2015, a process for a provider to override the step therapy or fail-first protocol of the payor.

Section 19-108.2(f) requires MHCC to establish by regulation a process through which a payor or provider may be waived from attaining the benchmarks relating to preauthorization of health care services for extenuating circumstances.

Although not cited by the MHCC, § 19-109(a) of the Health – General Article authorizes MHCC to adopt regulations to implement provisions of law governing the regulation of health care planning and systems.

In addition, § 15-142 of the Insurance Article prohibits health insurance carriers, including carriers that provide prescription coverage through a PBM, from imposing a step therapy or fail-first protocol on an insured or enrollee if the step therapy drug has not been approved by the FDA for the medical condition being treated or a prescriber provides supporting medical information to the entity that a prescription drug covered by the entity was ordered within the past 180 days and was effective in treating the insured’s or enrollee’s disease or medical condition. Section 15-142(a) defines “supporting medical information” in a manner that is reflected in the regulations.

With the addition of § 19-109(a) of the Health – General Article and § 15-142 of the Insurance Article, the authority cited by MHCC is correct and complete. The regulations comply with the legislative intent of the law.

Fiscal Analysis

There is no fiscal impact on State or local agencies beyond that already assumed in the fiscal and policy note for Chapters 316 and 317 of 2014.

Agency Estimate of Projected Fiscal Impact

The regulations implement Chapters 316 and 317 of 2014, which establish requirements for step therapy or fail-first protocols imposed by health insurers, nonprofit health service plans, and health maintenance organizations (collectively known as carriers), including carriers that provide coverage for prescription drugs through a pharmacy benefits manager. Under Chapters 316 and 317, the Maryland Health Care Commission must work with payors and providers to attain benchmarks for overriding a payor's step therapy or fail-first protocol. By July 1, 2015, each payor that requires a step therapy or fail-first protocol must establish a process for a provider to override the protocol. The Acts also repeal obsolete reporting requirements regarding the status of obtaining other benchmarks. The department advises that the regulations have no impact on State or local governments. The Department of Legislative Services concurs and notes that any fiscal impact has already been assumed in the fiscal and policy note for Chapters 316 and 317. This note assumed that special fund expenditures for the commission would increase by \$25,000 in fiscal 2015 and 2016 to hire a vendor to collaborate with payors to develop specifications and conduct testing of override processes and validate and audit the override processes.

Impact on Budget

There is no impact on the State operating or capital budget.

Agency Estimate of Projected Small Business Impact

The department advises that the regulations have minimal or no economic impact on small businesses in the State. The Department of Legislative Services concurs and notes that any fiscal impact has already been assumed in the fiscal and policy note for Chapters 316 and 317.

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