Regulatory Analysis for Benefit Determination and Utilization Review
230-RICR-20-30-14

RHODE ISLAND DEPARTMENT OF BUSINESS REGULATION
Office of the Health Insurance Commissioner

Introduction

The Office of the Health Insurance Commissioner (OHIC) was created by the Rhode Island General Assembly in 2004. The agency is charged with protecting consumers, ensuring fair treatment of health care providers, guarding the solvency of insurers, and improving the health care system as a whole. OHIC has played a leading role in efforts to improve the affordability and quality of health care in Rhode Island through placing regulatory requirements on commercial insurers to support a host of delivery system transformation and payment reform initiatives.

Reason for Regulatory Action

The purpose of this regulation is to enforce the Office of the Office of Health Insurance Commissioner jurisdiction and statute RIGL 27-18.9, the Benefit Determination and Utilization Review Act (the Act) effective on January 1, 2018. Prior to OHIC's jurisdiction, similar protections of the Act and subsequent regulations were under the jurisdiction of the Rhode Island Department of Health (HEALTH). The current Act reflects not only the change to OHIC's jurisdiction but reflects changes to bring the Act to current national protective standards to assure that benefit determination agencies maintain timely approval and payment for covered health care services to health care entity beneficiaries. In addition, the act and the clarity provided for in these regulations assure quality, continuity and reasonable access to covered benefits are maintained as health care entities and its review agents engage in benefit determination reviews. The statute was updated accordingly, and the proposed regulations designed and developed to clarify, for the benefit determination agencies, the expectations in order to comply with mandated requirements of the Act.

The below regulatory analysis is required by the Rhode Island Administrative Procedures Act, R.I. Gen. Laws 42-35-2.9.

Regulatory Development

While constructing the Benefit Determination and Utilization Review regulation**,** the Office considered a range of alternatives, including a review of past regulations and enforcement of the Act and subsequent regulations while under the Rhode Island Department of Health, existing Rhode Island health insurance regulations and policies of related subject matter, departmental experience, National Association of Insurance Commissioners B Committee Health regulations and industry best practice.

This proposed regulation considered other logistical methods and timeframes for information retention and protection. The Office assessed that the proposed provisions are sufficient to both protect individual's privacy and maintain the ability to implement the consumer protective nature of the statute while considering the interface with other OHIC responsibilities in related insurance statutes and regulations addressing health insurance affordability.

Stakeholder Analysis

The stakeholders effected by the proposed regulation fall into four categories: consumers,

providers, insurance companies and benefit review agencies. The proposed regulations will impose responsibilities on all health care entities and review agencies subject to the jurisdiction of the Commissioner. RIGL 27-18.9 defines "health care entity" and/or "review agency" as:

"an insurance company licensed, or required to be licensed, by the state of Rhode Island or other entity subject to the jurisdiction of the commissioner or the jurisdiction of the department of business regulation that contracts or offers to contract, or enters into an agreement to provide, deliver, arrange for, pay for, or reimburse any of the costs of health care services, including, without limitation: a for-profit or nonprofit hospital, medical or dental service corporation or plan, a health maintenance organization, a health insurance company, or any other entity providing health insurance, accident and sickness insurance, health benefits, or health care services." And

"Review agent" or "Review Agency" or "Agency" means a person or health care entity performing benefit determination reviews that is either employed by, affiliated with, under contract with, or acting on behalf of a health care entity."

As such, review agencies acting as a delegate of a health care entity or a health care entity acting as a review agency conduct benefit review determinations in order to properly determine payment for covered services. Benefit review determinations include both administrative and non-administrative decisions. Administrative benefit determinations do not require the use of medical judgment or clinical criteria in determining whether a benefit is covered whereas non-administrative or utilization review determinations require the use of medical judgment or clinical criteria to determine whether a service being review is medically necessary and/or appropriate. BDR applies to all types of insurance markets and benefit categories to include but not limited to medical coverage, behavioral health, dental, pharmacy, and vision coverage, etc. Thus, the largest constituency affected by the proposed regulations are the individual consumers (or "beneficiaries") who enjoy status as "a policy holder subscriber[s], enrollee[s], or other individual[s] participating in a health benefit plan."

Based on enrollment data submitted by the entities subject to the requirements of RIGL 27-18.9 there are 670,619 enrollees of network plans situsued in Rhode Island. The 670,619 enrollees do not reflect discrete individuals, nor does the figure reflect Rhode Island residents only. Purchasers of insurance frequently combine plans (major medical, dental, vision) from different sources and cover residents of neighboring states who work in Rhode Island. To narrow our focus to Rhode Island residents who have standing in this analysis, we draw from enrollment data collected annually from major medical plans. As of April 2018, there were 177,866 Rhode Island resident members of fully insured major medical plans among the four major insurers. This figure understates the number of consumers with standing in this analysis because it does not include enrollment among small insurers, nor does it account for other combinations of coverage, in which a person may not have major medical coverage but has some other form of coverage, such a dental. These individuals will benefit from the oversight of this benefit review determination process and the consumer protections guaranteed by the proposed regulation. The requirements set in these regulations for a streamlined and fair denial of care and appeal process assures the consumer adequate due process and assurance that necessary care is rendered and paid for in a timely manner.

Rhode Island's medical service providers, across an array of services (medical, dentistry, ophthalmology, etc.), are a significant stakeholder group with standing in this regulatory analysis. The regulatory requirements imposed on health care entities will impact provider's ability to have timely access to needed services and treatment of patients. Benefit review determination oversight via these regulations set requirements for review agencies so as not to impede care found necessary by the ordering provider and have a decision-making process for covered benefits that is aligned with the best interest of the consumer/patient. These regulations also outline an objective appeal process that can be effectively used by both consumers, a consumer representative and/or an ordering provider. Establishing appeal guidelines to be used by all review agencies allows for efficiency and effectiveness for all stakeholders to include administrative cost savings.

As a stakeholder, health care entities certified by OHIC are affected by the proposed regulation. The health care entities will be required to comply the benefit review determination regulations. The cost of compliance should not significantly differ from what was previously required under the Department of Health regulation of these health care entity benefit review processes. In addition, savings will be realized as these regulations have interfaced both federal and state requirements for this benefit review process.

Description of Proposed Regulation

In making amendments to existing provisions within the Benefit Determination and Utilization Review proposed regulation, the Office improved the ease of compliance by eliminating non-essential content and clarifying points of potential confusion for regulated parties. It is within OHIC's authority per statute and in the best interest of the consumer to promote the effective and efficient enforcement of the Act via these regulations.

OHIC added definitions to the Benefit Determination and Utilization Review regulations when the terms used in key portions of the statute existed in statute, but definitions were not provided for in the Act. The definitions that were added are common to either other Rhode Island insurance statutes, regulations and when not available at the state level, are consistent with standard definitions used by insurance carriers or national standard. The definitions added are; active treatment, covered service, material change, peer reviewer, participating provider/network provider, reconsideration and systemic change. Additionally, in definitions direct from statute, the Office added clarifying language and/or a word to further explain its meaning. For example, review agent defined in statute and OHIC added "or review agency" or "agency" as all of these terms are used synonymously when describing a person or health care entity that performs benefit determination reviews. Also, for the definition of non-administrative adverse benefit determination, OHIC added utilization review determination to it for ease of read given that this term more commonly used in the affected marketplace.

The term delegate is defined in the statute, but the body of the statute does not establish rules around delegate functioning. The definition states that regulations and further guidance is warranted. Historically the functions defined in Section 14.5 of these proposed regulations were governed by the Rhode Island Department of Health establishing that benefit determination review agents were regulated in the same manner for any delegated activity. This is also considered industry standard. From a financial perspective, this is the most effective and efficient

way to address compliance for mandated activities delegated to another party by the benefit determination review agent, otherwise consideration would have to be given to regulating another body of entities which, in turn, costs the industry more money. Such consideration would increase OHIC workload as well as delay certifications, recertifications and any material change approvals adversely affecting function of carriers in addition to services provided to its consumers.

OHIC has chosen a two-year cycle for recertification of the sixty-three (63) currently provisionally certified benefit determination review organizations (BDRs) given the historical degree of changes in both state and federal statutes affecting the statutory requirements. This cycle is also consistent with how often benefit determination review organizations were re-certified in the past. This will also allow effective and efficient compliance monitoring of systemic and material changes affecting BDRs, some prompted by federal and state statutory changes and the remaining due to internal BDR changes. There is a cost savings to both OHIC and the BDRs as there is only a re-certification filing fee of $250.00 and will minimize interim material modification filings that result in not only a filing fee but billing by OHIC for its time in reviewing the systemic and material changes.

Section 14.4(F) of the proposed regulation is based on the Act 27-18.9-4(3) requiring that both administrative and non-administrative benefit determination review agents have a complaint and grievance resolution process acceptable to the Commissioner. Historically, for matters of complaints under the jurisdiction of OHIC, thirty (30) calendar days is the standard. In section 14.4(F) it sets forth that review agencies must communicate with beneficiaries its complaint and grievance processes. This maintains current processes to allow for both review agents and OHIC to be responsive to matters important to access to care, network adequacy and availability, as well as continuity and quality of care. This section is also consistent with OHIC's Network Plan Regulation (230-RICR-20-30-9) to ensure compliance and allow for flexibility.

In section 14.6(B)(2) of the proposed regulation, OHIC provides clarification to the agreement between the attending provider and the review agent. The agreement between the two must be independent and evidenced by the review agent. Also, section (4)(c) was added to provide clarification for pre-service claim notifications. In section 14.6(D), OHIC addresses review agents' clinical criteria that is used to make determinations. The clinical criteria that is utilized by review agents must comply with the requirements set forth in the regulation to include a process to incorporate and consider local variations to national standards. This section on the review agents' making utilization decisions, more specifically the clinical criteria piece, was based off of the recommendations of the Administrative Simplification Workgroup (ASWG) led by OHIC. The ASWG was comprised of all stakeholders (health care entities, review agencies, professional providers, facility providers, behavioral health associations, and consumer advocates) who met over a two-month period to assess this matter; issuing a final report to the Commissioner. The final decision based on the Admin Simp Workgroup was then determined by the Commissioner and set forth within these regulations.

In section 14.7 of the proposed regulation, OHIC clarifies the reconsideration process within the internal process for review agents and beneficiaries. This is an important clarification as federal statute was utilized to encompass both individual and group markets' internal appeal rights. The reconsideration section further explains the timeframes for both review agent and complainant during the appeals process. Regarding RIGL 27-18.9-7, the Office has interpreted this section from the perspective of consumer protection explaining the internal appeal process to align with the reconsideration process. This clarification is more in line with the timelines previously used by

RIDOH and creates a guardrail of forty-five (45) days based on the statute for reconsiderations. OHIC also believes it allows for review agency flexibility for implementation while not conceding consumer protections and due process. In addition to the reconsideration process in section 14.7, this section also addresses the appeal of an adverse benefit determination decision when a drug is not on the formulary. This section is an interface of both state and federal statute for an exception process via appeal for pharmaceuticals that are not on formulary but that are medically necessary.

In section 14.8 of the proposed regulation, OHIC elucidates the external appeal process. More specifically OHIC includes explicit external appeal fees for adverse benefit determinations, including excepted benefits as defined by federal law. This section also addresses the external appeals process for non-formulary drugs which differs slightly from other external appeal process for its timelines in exigent circumstances. This section again, interfaces state with federal requirement as allowed in state statute.

Regulatory Analysis

Based on the provisions of the proposed regulation, OHIC has determined that there are minimal overall costs to the benefit determination review organizations and providers, and great benefits to the consumers in the following areas:

- Defining and clarifying delegate requirements
- Limiting jurisdiction to benefit determination activity of a RI licensed insurer eliminating cross jurisdictional oversight by multiple states.
- Establishing a two-year cycle for recertification of network plans
- Creating a mechanism in the complaint and grievance process around communication for consumers
- Assuring network adequacy for consumers

Through defining and clarifying health care entity and delegate requirements this will keep the overall costs down by keeping the health care entities responsible for all of their activities. If this process was not in place, it would generate more costs to regulate the entities that are no longer defined to be under Rhode Island jurisdiction as they are now under the state in which the insurance product is offered. Previous regulatory activity under the RI Department of Health allowed more than one states appeal process to be used, creating a duplicative and more costly process for the carrier and potentially the appellant. Additionally, there would be no additional benefit in duplicating regulatory oversight for the appellant. Finally, only those delegates performing functions for a licensed insurer in Rhode Island would fall under RI jurisdiction thereby also minimizing cross state duplication.

The two-year recertification process would keep the cost down of interim filings to correct application documents.

In establishing the communication process for the benefit determination review agents compliant and grievance process there is no additional costs as it is industry standard. The benefit is the communication between the consumer and their health care entity and/or the review agent, this provides with the ability to address carrier issues. The consumer can better use their benefits and

receive timely responses from their carriers, in addition to informing the carriers of any issues (i.e. provider, eligibility program).

In developing the rules for Benefit Determination Review Agents, it was the OHIC's goal to streamline content and provide added clarity consistent with the applicable statutes and OHIC's existing procedural rules and practices.

Monetizing the above benefits and costs accruing to stakeholders from the proposed regulation is not a straightforward task. In this case, the cost side of the social accounting ledger is slightly more tractable than the benefit side. The costs of the proposed regulation include the direct costs of compliance to health care entities acting directly as a review agent or in delegating benefit review activities to a separate review agency and as stated in RIGL 27-18.9-3, which allows the Commissioner to charge health care entities for the costs of the program. Prior to the transition of the Benefit Determination and Utilization Review Act to OHIC the Department of Health administered a similar program funded by an assessment on health care entities. Therefore, the core cost of the program is built into the status quo. The proposed regulations may cause some marginal cost to health care entities' administration and operations. For example, health care entity or review agency, may increase administrative burden on the health care entities and result in additional administrative costs. The marginal cost of compliance is unlikely to be significant.

The benefits afforded by the proposed regulation are harder to quantify. OHIC's oversight will ensure compliant benefit review agency activity. One of the key benefits of the proposed regulation is timely and fair access to necessary health care services for consumers. In general, timely and fair access to health care services is associated with improved outcomes in terms of morbidity and mortality. OHIC feels strongly that the benefit to cost ratio associated with the proposed regulation is greater than one.