Concise Explanatory Statement

Rhode Island Government Register

In accordance with the Administrative Procedures Act, R.I. Gen. Laws § 42-35-2.6, following is a concise explanatory statement:

AGENCY: Rhode Island Office of the Health Insurance Commissioner (OHIC)

DIVISION:

RULE IDENTIFIER: 230-RICR-20-30-14

REGULATION TITLE: Benefit Determination and Utilization Review

RULEMAKING ACTION: Adoption

REASON FOR RULEMAKING:

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 review 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 review agencies, the expectations in order to comply with mandated requirements of the Act.

OHIC is proposing to establish standards and procedures for the certification/recertification process of Benefit Determination Review organizations, and to generally assist OHIC in carrying out the administration and enforcement of the terms and provisions of the Benefit Determination and Utilization Review Act, R.I. Gen. Laws § 27-18.9 et seq. The proposed regulation supplements the statutory requirements by:

- Specifying the application requirements for review agent certifications in Rhode Island;
- Limiting jurisdiction to benefit determination activity of a RI licensed insurer eliminating cross jurisdictional oversight by multiple state;
- Establishing requirements for delegates of a review agency as well as utilization review and benefit determination requirements for an agency to follow;
- Establishing administrative and non-administrative procedural requirements;
- Setting requirements for general administrative and non-administrative benefit determination;

- Establishing internal appeal and external appeal requirements;
- Setting reporting requirements for review agents;
- Establishing procedures for the renewal of certifications;
- Setting fees for initial and renewal certifications.

A. Summary of Post-Comment Changes. There are several differences between the text of the proposed rules as published in accordance with R.I. Gen. Laws § 42-35-2.7 and the rule as adopted. These changes are all consistent with, and a logical outgrowth of, the amendments in the notice of proposed rulemaking in accordance with R.I. Gen. Laws § 42-35-6.1. In addition to this summary of changes, a redlined document showing the exact changes is attached.

1. *Definitions* - §14.3(A)(24) & (26) – Commentary was received regarding the definition of "material change", requesting modification as the Network Plan regulation covered certain aspects that were not relevant to the proposed rule. OHIC has made the appropriate changes and removed 24(a-d, f) as well as revised to further clarify the meaning of material change for BDR. Additionally, commentary was received regarding the definition of "peer reviewer". The comment requested the definition be expanded to allow for the same or greater licensure status. OHIC has made changes to peer reviewer and added "at least" before "the same licensure status as the ordering provider" to adhere to this modification request.
2. *Definitions* - §14.3(A)(37) – Commentary was received regarding modification to the definition of "systemic change". OHIC removed "beneficiaries, a group of providers, an entire specialty provider type, a hospital, or a facility provider" and replace with "claimants" as the definition of claimant includes all of these groups. Additionally, comments were received requesting specific examples of what would be considered a systemic change. OHIC believes that providing specific examples would be limiting to the Office. OHIC determines when systemic changes become material. It is important that systemic change remain as stated in the proposed regulation.
3. *General Requirements* - §14.4 – Commentary was received addressing the challenges faced by individuals transitioning between care settings and the impact that such care transitions can have on the health of the individual. OHIC has the broad authority to establish standards to ensure continuity of care is given consideration in policies and procedures. Therefore, the commentary suggested the inclusion of a new section pertaining to continuity of care. OHIC agrees and has made changes to the proposed rule by adding a section between 14.4(F) and (G).
4. *Benefit Determination General Requirements* - §14.6(A)(1) and (A)(2) – Commentary was received requesting further clarification and modification of these sections. OHIC has made changes to meet the statutory requirements of initiating a claim for section 14.6(A)(1) and to clarify section 14.6(A)(2) by removing "concurrent claims".
5. *Benefit Determination General Requirements* - §14.6(B)(2)(b) – Commentary was received requesting clarity on the peer-to-peer process taking place prior to any adverse benefit determination and not during an approval. OHIC agrees with this commentary and has made the appropriate changes to reflect that the peer-to-peer is during the adverse benefit determination process.

6. *Benefit Determination General Requirements* - §14.6(D)(3)(a-b) – Commentary was received requesting modifications to the parties that review agents are required to solicit input from for clinical criteria. OHIC has made changes to these sections to highlight its intent to have a proactive and reactive process for clinical criteria. Also, with the addition of "employers, sponsors of health plans, or interested parties", OHIC has expanded and clarified who is able to provide input on clinical criteria based on public comment recommendations. While all commentary has to be considered, OHIC has clarified that active solicitation is only required from local participating providers.
7. *Internal Appeal and Reconsideration Requirements* - §14.7(C)(2-3) – Commentary was received requesting to allow review agents to have a different reconsideration process for non-administrative and administrative benefit determinations. OHIC removed C(2) which required the same process for all adverse benefit determinations. For section C(3), OHIC leaves the reconsideration process up to the carriers to determine the implementation of the process, but it should made in an appropriate manner acceptable the Commissioner.
8. *Internal Appeal and Reconsideration Requirements* - §14.7 (D)(3) – Commentary was received requesting a specific timeframe to inform the claimant prior to the internal appeal decision. While OHIC does not want to be prescriptive with a specific timeframe but had added language to clarify this section.
9. *Internal Appeal and Reconsideration Requirements* - §14.7(H) – Commentary received requesting the removal of "non-urgent or non-emergent" as it is duplicative and referenced in a different part of the proposed rule. OHIC has made the change for clarification purposes.
10. *Internal Appeal and Reconsideration Requirements* - §14.7(K) – Commentary was received on the process for a drug that is not on the formulary. OHIC has made changes to clarify that the process for a drug that is not on the formulary is a request for coverage and not an appeal.
11. *Internal Appeal and Reconsideration Requirements* - §14.7(O) and (O)(2) – Commentary was received requesting clarification on these sections as they appear to apply to all benefit determination and not only adverse benefit determinations. OHIC agrees that this is the intent of section (O) and has made the appropriate changes. Additionally, commentary was received regarding section (O)(2) being duplicative of the definition of peer reviewer. OHIC agrees and has made the appropriate changes throughout this section by removing (O)(2).
12. *Internal Appeal and Reconsideration Requirements* - §14.7(P)(2) – Commentary was received requesting clarification on the circumstances in which peer reviewer contact information must be provided to the ordering provider. OHIC has made changes to further elucidate when the agency must provide contact information of the peer reviewer.
13. *Internal Appeal and Reconsideration Requirements* - §14.7(P)(3)(a-b) – Commentary was received requesting changes to this section to address the two reasonable attempts to satisfy the requirement of a two-way direct communication with a peer reviewer. OHIC has made changes to address these comments and provide further direction.
14. *External Appeal of Non-Administrative Benefit Determinations Requirements* - §14.8(F) – Commentary was received stating that the current cost not making it economically infeasible. OHIC has made changes to the fee for an external appeal to account for the excepted benefits and the comments the Office received.

15. *External Appeal of Non-Administrative Benefit Determinations Requirements* - §14.8(K)(1) – Commentary was received requesting removal of language to allow for flexibility of who will notify the claimant that their request has been forwarded to the independent review organization (IRO). OHIC agrees and has made the appropriate change as the intent is to ensure the timeframe but not specifically who is sending out the notification.
16. *External Appeal of Non-Administrative Benefit Determinations Requirements* - §14.8(L)(1) – Commentary was received regarding a correction to the language. OHIC corrected the language and replaced "reconsideration" with "external appeal" as that was the intent.

B. Summary of Comments Not Resulting in Regulatory Language Changes. Below is a summary of other public comments received (public hearing testimony, in addition to oral and written public comments) that did not result in changes to the text of the Regulation and a brief description of the Office reasons for not making any such changes after due consideration.

1. *General Requirements* - §14.4(B)(5) – Commentary was received stating that these requirements exist in the Network Plan regulation and are sufficient to capture systemic changes related to review agents. After carefully reviewing the commentary, OHIC certifies both network plan and benefit determination review agents and while functions are interfaced, they have separate requirements and processes for each. Therefore, OHIC requires this information be present in the proposed rule.
2. *General Requirements* - §14.4(F)(3) – Commentary was received requesting OHIC to define "reasonable communication on an annual basis". OHIC leaves the interpretation up to the carriers in order to have flexibility in their policies and procedures regarding communication with their beneficiaries.
3. *Benefit Determination General Requirements* - §14.6 (B)(3) – Commentary was received requesting subsections that address administrative benefit determinations. After carefully reviewing the commentary, OHIC asserts that this section only applies to utilization review therefore the changes would not be appropriate.
4. *Benefit Determination General Requirements* - §14.6(D)(4) – Commentary was received requesting the removal of this language to protect the intellectual property of clinical criteria. After carefully reviewing the commentary, OHIC is not requesting any propriety or confidential information as this is protected in statute. OHIC is only requesting a general description of clinical criteria, not full criteria.
5. *Reporting* - §14.9 – Commentary was received requesting further clarity on the reporting requirements of review agents. After carefully reviewing the commentary, OHIC believes this clarity is better within instructions created by the Office after providing carriers the opportunity for comment.
6. *General Comments* – Commentary was received requesting an effective date of the proposed rule. OHIC is unable to provide a definitive date as the Secretary of State and Office of Regulatory Reform dictate the process for all state regulations. Also, commentary was received asking for confirmation that the proposed rule applies to all pharmaceutical appeals regardless of whether or not they are expedited. OHIC was not directed to a particular section in the proposed rule or a particular change, however, there

is a standard appeal process which includes all services (medical, surgical, pharmacy, etc.) for which there is an expedited and standard appeal process and timeframes. Additionally, there is a non-formulary process for which is outside the standard/expedited with its own timeframes.

REGULATORY ANALYSIS:

Based on the provisions of the proposed regulation, OHIC has determined that there are minimal overall costs to the benefit determination review agencies and health care entities, and great benefits to consumers. In developing the rules for Benefit Determination Review organizations (BDR), it was OHIC's goal to streamline content and provide added clarity consistent with the applicable statutes and OHIC's existing procedural rules and practices.

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.

Marie Ahern

Commissioner's Signature

5/2/2019

Date

230-RICR-20-30-14

TITLE 230 - DEPARTMENT OF BUSINESS REGULATION

CHAPTER 20 - INSURANCE

SUBCHAPTER 30 - HEALTH INSURANCE

Part 14 - Benefit Determination and Utilization Review

14.1 Authority

These rules and regulations are promulgated pursuant to R.I. Gen. Laws § 27-18.9 entitled Benefit Determination and Utilization Review Act (the Act).

14.2 Purpose and Scope

A. It is in the best interest of the public that those individuals and health care entities involved with the determination of health plan benefit determinations, administrative and non-administrative, in our state meet the standards set forth in R.I. Gen Laws § 27-18.9 (the Act) and this Part;

B. To establish reasonable standards for review agencies to ensure the timely approval of and payment for covered health care services to health care entity beneficiaries;

C. To protect health care entity beneficiaries from benefit determination processes that may unreasonably impede access to covered health care services;

D. To require health care entities and review agencies to improve and maintain coordination of benefit determination activities among all stakeholders and to the benefit of beneficiaries; and

E. Nothing in the Act and this Part is intended to prohibit a health care entity or its review agencies from performing medical necessity determinations or maintaining processes to assess the accuracy of benefit coverage for its beneficiaries.

14.3 Definitions

A. As used in this Part:

1. "Adverse benefit determination" means a decision not to authorize a health care service, including a denial, reduction, or termination of, or a failure to provide or make a payment, in whole or in part, for a benefit. A decision by a review agent to authorize a health care service in an alternative setting, a modified extension of stay, or an alternative

treatment shall not constitute an adverse benefit determination if the review agent and provider are in agreement regarding the decision. Adverse benefit determinations include:

a. "Administrative adverse benefit determinations," meaning any adverse benefit determination that does not require the use of medical judgment or clinical criteria such as a determination of an individual's eligibility to participate in coverage, a determination that a benefit is not a covered benefit, a determination that an administrative requirement was not followed, or any rescission of coverage; and

b. "Non-administrative adverse benefit determinations," or “utilization review adverse benefit determinations,” meaning any adverse benefit determination that requires or involves the use of medical judgment or clinical criteria to determine whether the service being reviewed is medically necessary and/or appropriate. This includes the denial of treatments determined to be experimental or investigational, and any denial of coverage of a prescription drug because that drug is not on the health-care entity's formulary.

2. "Appeal" or "internal appeal" means a subsequent review of an adverse benefit determination upon request by a claimant to include the beneficiary or provider to reconsider all or part of the original adverse benefit determination.

3. “Authorization” means a review by a review agent, performed according to the Act and this Part, concluding that the allocation of health care services ordered by a provider, given or proposed to be given to a beneficiary, was approved or authorized.

4. "Authorized representative" means an individual acting on behalf of the beneficiary and shall include: the ordering provider; any individual to whom the beneficiary has given express written consent to act on his or her behalf; a person authorized by law to provide substituted consent for the beneficiary; and, when the beneficiary is unable to provide consent, a family member of the beneficiary. Ordering provider shall have the same meaning as attending provider for purposes of this Part.

5. "Beneficiary" means a policy holder subscriber, enrollee, or other individual participating in a health benefit plan.

6. "Benefit determination" means a decision to approve or deny a request to provide or make payment for a health care service or treatment. Benefit determinations include:

a. “Administrative benefit determinations”, meaning any benefit determination that does not require the use of medical judgement

or clinical criteria such as a determination of an individual's eligibility to participate in coverage, a determination that a benefit is or is not covered, a determination that an administrative requirement was or was not followed, or any determination of coverage; and

b. “Non-administrative benefit determinations”, or “utilization review benefit determinations”, meaning any benefit determination that requires or involves the use of medical judgment or clinical criteria to determine whether the service being reviewed is medically necessary and/or appropriate. This includes the denial or approval of treatments determined to be experimental or investigational, and any denial or approval of coverage of a prescription drug because that drug is not on the health care entity's formulary.

7. "Certificate" means a certificate granted by the Commissioner to a review agent/agency meeting the requirements of this chapter.

8. “Claim” means a request for plan benefit(s) made by a claimant in accordance with the health care entity's reasonable procedures for filing benefit claims. This shall include pre-service, concurrent, and post-service claims.

9. “Claimant” means a health care entity participant, beneficiary, and/or authorized representative who makes a request for plan benefit(s).

10. “Commissioner" means the Commissioner of the Office of the Health Insurance Commissioner.

11. "Complaint" or "grievance" means an oral or written expression of dissatisfaction by a beneficiary, authorized representative, or provider. The appeal of an adverse benefit determination is not considered a complaint or grievance.

12. “Concurrent assessment” means an assessment of health care services conducted during a beneficiary's hospital stay, course of treatment or services over a period of time, or for the number of treatments. If the medical problem is ongoing, this assessment may include the review of services after they have been rendered and billed.

13. "Concurrent claim" means a request for a plan benefit(s) by a claimant that is for an ongoing course of treatment or services over a period of time or for the number of treatments.

14. “Covered service" or "covered benefit" means those health care services to which a beneficiary is entitled under the terms of the health benefit plan.

15. “Delegate" means a person or other party authorized pursuant to a delegation of authority or re-delegation of authority, by an agency to perform one or more of the functions and responsibilities of an agency set forth in the Act or regulations or guidance promulgated thereunder.

16. “Emergency services" or "emergent health care services" means those resources provided in the event of the sudden onset of a medical, behavioral health, or other health condition where the absence of immediate medical attention could reasonably be expected, by a prudent layperson, to result in placing the patient's health in serious jeopardy, serious impairment to bodily or mental functions, or serious dysfunction of any bodily organ or part.

17. "External review" means a review of a non-administrative adverse benefit determination (including final internal adverse benefit determination) conducted pursuant to an applicable external review process performed by an independent review organization.

18. “External review decision” means a determination by an independent review organization at the conclusion of the external review.

19. "Final internal adverse benefit determination" means an adverse benefit determination that has been upheld by a plan or issuer at the completion of the internal appeals process or when the internal appeals process has been deemed exhausted as defined in R.I. Gen. Laws §27-18.9-7(b)(1).

20. "Health benefit plan" or "health plan" means a policy, contract, certificate, or agreement entered into, offered, or issued by a health care entity to provide, deliver, arrange for, pay for, or reimburse any of the costs of health care services.

21. “Health care entity" means 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. Entity shall have the same meaning as health care entity for purposes of this Part.

22. “Health care service" means and includes, but is not limited to: an admission, diagnostic procedure, therapeutic procedure, treatment, extension of stay, the ordering and/or filling of formulary or non-formulary medications, and any other medical, behavioral, dental, vision care

services, activities, or supplies that are covered by the beneficiary's health benefit plan.

23. "Independent review organization" or "IRO" means an entity that conducts independent external reviews of adverse benefit determinations or final internal adverse benefit determinations.

24. "Material change" means a systemic change determined by the Office to be a change, that could reasonably be expected to adversely affect the access, availability, quality or continuity of services for a significant number of beneficiaries of a health care entity to include, but not be limited to the following:

~~a. Termination of a hospital or facility contract;~~

~~b. Termination of professional provider contract(s);~~

~~c. Professional provider contract changes affecting any one professional provider specialty within any of the health care entity's network plans;~~

~~d. A change to the tiered products, or the multi-tiered, layered or multi-level network plan structures during a network plan contract year;~~

~~e~~a. Termination or transition of any benefit determination delegate; and

~~f. Surrender or withdrawal of any network plan holding a certificate under the Act or this Part; or~~

~~g~~b. Other operational and network plan changes that meet the definition of ~~material~~ systemic change relevant to benefit determinations.

25. "Office" means the Office of the Health Insurance Commissioner.

26. "Peer reviewer" means a review agency's licensed practitioner with at least the same licensure status as the ordering provider.

27. "Pre-service claim" means the request for a plan benefit(s) by a claimant prior to a service being rendered and is not considered a concurrent claim

28. "Participating provider" or "network provider" means a provider under contract with a health care entity, or one of its delegates, who has agreed under this contract to provide health care services to the health care entity's beneficiaries with an expectation of receiving payment, other than coinsurance, copayments, or deductibles from the beneficiary, only from the health care entity under the terms of the contract.

29. "Professional provider" or “professional practitioner” means an individual provider or health care professional licensed, accredited, or certified to perform specified health care services consistent with state law and who provides these health care services and is not part of a separate facility or institutional contract.

30. "Prospective assessment" and/or "pre-service assessment" means an assessment of health care services prior to services being rendered

31. "Provider" means a physician, hospital, professional provider, pharmacy, laboratory, dental, medical, or behavioral health provider, or other state-licensed or other state-recognized provider of health care or behavioral health services or supplies.

32. “Reconsideration” means a review during the appeal process of an adverse benefit determination based on the submission of additional information or a peer-to-peer discussion. A reversal of an adverse benefit determination outside of the appeals process is not a reconsideration.

33. "Retrospective assessment" and/or "post-service assessment" means an assessment of health care services that have been rendered. This shall not include reviews conducted when the review agency has been obtaining ongoing information.

34. "Retrospective claim" or "post-service claim" means any claim for a health plan benefit that is not a pre-service or concurrent claim.

35. "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.

36. "Same or similar specialty" means a practitioner who has the appropriate training and experience that is the same as or similar to the attending provider in addition to experience in treating the same problems to include any potential complications as those under review.

37. "Systemic change" means any modification of an agency’s or agency delegate’s benefit determination policies and/or procedures that may adversely affect ~~beneficiaries, a group of providers, an entire specialty provider type, a hospital, or a facility provider~~ claimants~~;~~ or any agency’s or agency delegate’s modification that may impact a significant portion of its beneficiaries’ access to covered health care services, the availability of care, or the quality and continuity of care.

38. "Therapeutic interchange" means the interchange or substitution of a drug with a dissimilar chemical structure within the same therapeutic or pharmacological class that can be expected to have similar outcomes and

similar adverse reaction profiles when given in equivalent doses, in accordance with protocols approved by the president of the medical staff or medical director and the director of pharmacy.

39. "Urgent health care services" includes those resources necessary to treat a symptomatic medical, mental health, substance use, or other health care condition that a prudent layperson, acting reasonably, would believe necessitates treatment within a twenty-four (24) hour period of the onset of such a condition in order that the patient's health status not decline as a consequence. This does not include those conditions considered to be emergent health care services as defined in this Part.

40. "Utilization review" or “non-administrative review” means the prospective, concurrent, or retrospective assessment of the medical necessity and/or appropriateness of the allocation of health care services of a provider, given or proposed to be given, to a beneficiary. Utilization review does not include:

    a. The therapeutic interchange of drugs or devices by a pharmacy operating as part of a licensed inpatient health care facility; or

    b. The assessment by a pharmacist licensed pursuant to the provisions of R. I. Gen. Laws § 5-19.1 and practicing in a pharmacy operating as part of a licensed inpatient health care facility, in the interpretation, evaluation and implementation of medical orders, including assessments and/or comparisons involving formularies and medical orders.

41. "Utilization review plan" means a description of the standards governing utilization review activities performed by a review agent.

14.4 General Requirements

A. A review agent must establish and submit to the Office standards and procedures for its benefit determination activity that demonstrates compliance with the Act and this Part to include administrative and non-administrative benefit determinations as defined in this Part. This shall be submitted through a certification, recertification and material change process determined by the Commissioner, including as set forth in this Part.

B. A review agent operating in Rhode Island shall provide evidence of adherence to the following:

    1. That it shall not conduct benefit determination reviews in the state unless the Commissioner has granted the review agent a certificate pursuant to the Act and this Part;

2. Individuals shall not be required to hold a separate review agent certification under the Act or this Part when acting as either an employee of, an affiliate of, a contractor for, or otherwise acting on behalf of a certified review agent, however, the review agent shall be responsible for these individuals in the same manner that the review agent is responsible for its delegates under the Act and this Part;

3. Submission of a recertification application every two (2) years in form and content consistent with instructions issued by the Office for that purpose;

4. Notification and explanation to the Office at least thirty (30) calendar days prior to implementation of any systemic change to any of the certified review agent's operations to include the information on file with the Office;

5. Upon a determination by the Office that a systemic change constitutes a material change, shall file an application consistent with instructions and requests for information issued by the Office for that purpose; and

6. A systemic change determined by the Office to be a material change shall not be implemented until receipt of written approval for the material change by the Office.

C. A review agent applying for certification, recertification or material change approval shall provide information to the Office sufficient to enable the Office to evaluate compliance with the requirements of the Act and this Part according to instructions issued as a guidance document by the Office for that purpose.

D. The cost of the application processes (certification, recertification, and material change), application reviews, complaint processing, investigations, and other activities related to obtaining and maintaining review agency certifications shall be borne by the review agents, as determined by the Commissioner, including:

1. An application fee established by the Commissioner for each application processed, not to exceed five hundred dollars ($500), which must accompany each application.

2. Pursuant to R.I. Gen. Laws § 27-18.9-3(h), the total cost of obtaining and maintaining a certificate under this Act and in compliance with the requirements of the applicable rules and regulations shall be borne by the applicant and shall include one hundred and fifty percent (150%) of the total salaries paid to the personnel engaged in certifications and ensuring compliance with the requirements herein of this Part and the applicable rules and regulations.

3. Pursuant to R.I. Gen. Laws § 27-18.9-3(h), these monies shall be paid to the Commissioner to and for the use of the Office and shall be in addition to any taxes and fees otherwise payable to the state.

4. The Commissioner may not issue a certification, recertification, approval of a material change, or may suspend a currently certified review agent, if a review agent fails to pay any of the fees, assessments and costs noted above in a timely manner.

E. Pursuant to R.I. Gen. Laws § 27-18.9-3(e), a certificate issued under this Part is not transferable, and the transfer of fifty percent (50%) or more of the ownership of a review agent shall be deemed a transfer.

F. Review agents must maintain and submit to the Office its most current grievance and complaint process that adheres to and includes the following minimal requirements:

1. Written processes whereby the beneficiary, a beneficiary's authorized representatives, or health care providers may seek resolution of complaints and grievances, and other matters, of which the review agent has received oral or written notice;

2. Reasonable timeframes for the resolution of beneficiary, authorized representative of beneficiary, and provider complaints and grievances of not more than thirty (30) calendar days from the date the review agent receives the oral or written notice unless granted an extension by the Commissioner;

3. A substantiation to the satisfaction of the Commissioner that there is reasonable communication on an annual basis either directly or through the health care entity to the network plan beneficiaries and providers that explains the grievance and complaint process to include guidance for distinguishing between a complaint/grievance and a benefit determination appeal and the rights associated with each; and

4. Internal monitoring of complaints and grievances and reporting of complaints and grievances in form and content consistent with instructions issued by the Office for that purpose.

G. In accordance with the purpose section, RIGL 27-18.9-1, RIGL 27-18.8-3(b) and RIGL 27-9.1-4(a)(3-4), each agency shall perform its benefit determination and appeals processes defined in this Part, in a manner to ensure quality, access, and continuity of care (to include transition of care) and the welfare and safety of the patient.

H. Each agency shall develop, implement and maintain a quality assurance program that includes the agency's oversight of all activities, whether or not delegated, subject to the Act and this Part. This quality assurance program shall include a process to regularly evaluate and determine whether the agency's activities are being performed in a manner that maintains the quality of services delivered to its beneficiaries; and assures that the agency's activities do not adversely affect the delivery of covered services.

IH. Each review agent shall cooperate with all compliance reviews and investigations conducted by the Office.

JI. Each review agent shall ensure that all applicable federal and state confidentiality laws are followed.

14.5 Delegate Requirements

A. An agency must provide evidence to the Office of current state certification under the Act for each of its delegates, if any, to which the agency has delegated activity in accordance with this Part.

B. Each agency must maintain regular and meaningful oversight of each of its delegates to ensure every such delegate is in compliance with the Act's requirements, including but not limited to the following:

1. For any portion of the agency activity that is delegated, in part or whole, the agency shall be responsible for oversight and be held accountable for all activity delegated and for any non-compliance of its delegate with the Act and this Part.

2. Should the Commissioner determine that any delegated activity is non-compliant with this Part or other state and/or federal laws, the agency may be required by the Commissioner to re-assume or reassign the performance of the activity delegated.

3. The agency shall ensure through its delegation agreement or contract that it and the Office will have direct access to all the information held by the delegate that in its or the Office's determination could contribute to determining compliance with the Act and this Part as well as all other applicable state and federal laws and regulations.

14.6 Benefit Determination General Requirements

A. Each review agent must submit to the Office its policies and procedures in accordance with the Act that evidence adherence to the following:

1. In order to initiate a claim the claimant must have stated ~~The health care entity's claims procedures will be considered to have been followed by a claimant when a claimant makes a request for a benefit determination that includes~~ the claimant's name, specific medical condition or symptom and specific treatment, service, or product and submits such information to the proper claim processing unit;

2. In the event of a failure by a claimant to follow the health care entity's claims procedures for a pre-service claim ~~or concurrent claim~~, the health care entity or its review agent must comply with notification provisions in accordance with R.I. Gen. Laws § 27-18.9-5(a) and this Part.

a. For non-urgent and non-emergent pre-service claims ~~or concurrent claims~~:

(1) Notify claimant in writing of this failure as soon as possible and no later than five (5) calendar days following such failure; and

(2) This notification must also inform claimant of the specific claims procedures not complied with as well as the proper procedures to file a pre-service claim ~~or concurrent claim~~.

b. Notwithstanding the above, if the pre-service claim ~~or concurrent claim~~ relates to urgent or emergent health care services:

(1) The health care entity or its review agent must notify and inform claimant of the specific procedural failure and proper procedures to file a pre-service claim ~~or concurrent claim~~ within twenty-four (24) hours following the failure; and

(2) Notification may be oral, unless written notification is requested by the claimant.

3. In accordance with R.I. Gen. Laws § 27-18.9-4(a)(1), beneficiaries and providers shall be provided with a summary of its benefit determination review programs and adverse benefit determination criteria in a manner acceptable to the Commissioner that includes a summary of the standards, procedures, and methods to be used in evaluating proposed, concurrent, or delivered health care services;

4. In accordance with R.I. Gen. Laws § 27-18.9-4(a)(5), the requirement that no employee of, or other individual rendering or recommending an adverse benefit determination or appeal decision on behalf of the review agent or health care entity may receive any financial or other incentives based upon the number of denials of certification made by that employee or individual;

5. In accordance with R.I. Gen. Laws § 27-18.9-4(a)(6), the review agent has not entered into an understanding, a compensation agreement or a contract with its employees or agents whereby the compensation of its employees or its agents is based, directly or indirectly, upon a reduction of health care services or the charges for those services, a reduction of lengths of stays, or the use of alternative treatment settings;

6. An adverse benefit determination and internal appeals process consistent with R.I. Gen. Laws § 27-18.9-4(a)(7) and acceptable to the Office, whereby beneficiaries, authorized representatives, their physicians, or other health care service providers may seek prompt reconsideration or

appeal of adverse benefit determinations by the review agent according to all state and federal requirements;

7. In accordance with R.I. Gen. Laws § 27-18.9-4(a)(8), the health care entity or its relevant review agent has a mechanism to provide the claimant with a description of its claims procedures and any procedures for obtaining approvals as a prerequisite for obtaining a benefit or coverage for such benefit. This description should, at a minimum, be placed in the summary of benefits document and be available on the review agent's or the relevant health care entity's website and upon request from the claimant; and

8. All administrative benefit determination decisions and notifications shall be made within a reasonable period of time, considering circumstances, acceptable to the Commissioner. For utilization review determinations and notifications refer to § 14.6(B) and § 14.6(E) of this Part.

B. In accordance with R.I. Gen. Laws § 27-18.9 and this Part, review agents conducting utilization review shall comply with the following:

1. All initial, prospective, and concurrent non-administrative adverse benefit determinations of a health care service ordered by a physician, dentist, or other professional practitioner shall be made, documented, and signed by a licensed practitioner with the same licensure status as the ordering provider.

2. Review agents conducting utilization review are not prohibited from allowing appropriately qualified review agency staff from engaging in discussions with the attending provider, in accordance with the following:

a. The attending provider or health care facility may designate other individual(s) to speak on their behalf; and

b. Such a discussion prior to any adverse benefit determination may result in a voluntary modification of the attending provider's original request which shall not constitute an adverse benefit determination provided the following occurred and was documented by the review agent:

(1) The attending provider explicitly made a bona fide voluntary agreement to a change in his/her original order and/or explicitly made a bona fide voluntary agreement to an alternative level of care; or

(2) The attending provider's designee obtained and provided to the review agent documented consent from the attending provider that explicitly communicates the attending

provider's bona fide voluntary agreement in accordance with § 14.6(B)(2)(b)(1) above.

c. Such discussions shall not constitute a substitute for the required equivalent two-way direct communication required by this Part.

3. A review agent shall not retrospectively deny authorization for health care services provided to a beneficiary when an authorization had been obtained for that service from the review agent unless:

a. The authorization was based upon inaccurate information submitted to the review agent that was material to the review; or

b. The health care services were not provided consistent with the provider's submitted plan of care and/or any material restrictions clearly included in the prior approval granted by the review agent.

4. A review agent shall comply with the following notification timeline requirements in accordance with this Part:

a. For urgent or emergent health care service claims, benefit determinations (adverse or non-adverse) shall be made;

(1) As soon as possible taking into account exigencies; and

(2) No later than seventy-two (72) hours after receipt of the claim.

b. For concurrent claims;

(1) Benefit determinations (adverse or non-adverse) shall be made no later than twenty-four (24) hours after receipt of the claim; and

(2) Where the claim has been made to the agency at least twenty-four (24) hours prior to the expiration of the relevant period of time or number of treatments, benefit determinations (adverse or non-adverse) shall be made no later than twenty-four (24) hours after receipt of the claim and prior to the expiration of the period of time or number of treatments; and

(3) The agency must be available to conduct the concurrent review twenty-four (24) hours in advance of the expiration of the period of time or the number of treatments.

c. For pre-service claims, benefit determinations (adverse or non-adverse) shall be made:

(1) Within a reasonable period of time appropriate to the medical circumstances;

(2) Prior to the service being rendered; and

(3) No later than fifteen (15) calendar days after the receipt of the claim, provided that;

(4) The above time parameters set forth in § 14.6(B)(4)(c)(3) of this Part may be extended for up to fifteen (15) additional calendar days:

AA. When substantiated as being required by special circumstances; and

BB. When the claimant is noticed within the first fifteen (15) calendar-day period of the need for such extension.

d. For post-service claims, benefit determinations (adverse or non-adverse) shall be made:

(1) No later than thirty (30) calendar days after the receipt of the claim, provided that;

(2) The above time parameters set forth in § 14.6(B)(4)(d)(1) of this Part may be extended for up to fifteen (15) additional calendar days:

AA. When substantiated as being required by special circumstances; and

BB. When the claimant is noticed within the first thirty (30) calendar day period of the need for such extension.

5. In the event where there is insufficient information from a claimant for the agency to make a utilization review determination, the agency shall adhere to or ensure conditions in accordance with R.I. Gen. Laws § 27-18.9-6(a)(5) and this Part.

a. For urgent or emergent health care services to include pre-service and concurrent claims, the notice of insufficient information shall be sent to the claimant as soon as possible and not later than the timeframes set forth in R.I. Gen. Laws 27-18.9-6(a)(5).

b. For non-emergent pre-service, concurrent and post-service claims, the notice of insufficient information shall be sent to the claimant as

soon as possible and no later than the timeframes set forth in §27-18.9-6(a)(5)(ii).

c. In the event of insufficient information in a claim, timelines for decisions and notifications set forth in §14.6(B)(4) and (B)(5) of this Part, are paused from the date on which the notice is sent to the claimant and then restarted when the claimant responds to the request for information.

C. A review agent's utilization review policies shall include at a minimum the requirements stated in R.I. Gen. Laws § 27-18.9-4(b) and this Part.

D. In accordance with R.I. Gen. Laws § 27-18.9-7 and this Part, review agents making utilization review decisions shall evidence to the Commissioner and comply with the following:

1. The requirement that each review agent shall provide its clinical criteria to the Office upon request;

2. Use written clinical criteria and review procedures established according to nationally accepted standards, evidence-based medicine and protocols that are periodically evaluated and updated or other reasonable standards required by the Commissioner; and

3. Establish and employ a process to transparently incorporate and consider local variations to national standards and criteria identified in this Part including, without limitation, a process to incorporate input from local participating providers. As used in this Part, a process to incorporate and consider local variations to national standards and criteria shall mean a process that:

a. Affirmatively and meaningfully solicits, documents ~~tracks~~ and reasonably incorporates input from an objective, independent and diverse pool of local providers, including local participating providers or their representatives; and~~.~~ ~~Affirmative and meaningful solicitation shall include, without limitation, notice to consumer advocacy groups, healthcare professional associations and chronic disease associations concerning clinical criteria relevant to their organizations; and~~

b. Reasonably considers and ~~tracks~~documents ~~and meaningfully considers~~ input and information received from consumer advocacy groups, healthcare professional associations and chronic disease associations, employers, sponsors of health plans or other interested parties concerning clinical criteria.~~ relevant to clinical criteria received through benefit determination processes and complaint and grievance processes.~~

4. Ensure meaningful and reasonably understandable updated descriptions of clinical decision criteria are available to beneficiaries, providers, and the Office upon request as well as readily available and accessible on the health care entity's or the review agent's website.

E. Review agent notifications form and content requirements:

1. Health care entities and review agents shall comply with form and content notification requirements for adverse benefit determinations in accordance with R.I. Gen. Laws § 27-18.9-6(b) and this Part.

2. All review agent notification templates must be provided to the Office for review and approval by the Commissioner.

14.7 Internal Appeal and Reconsideration Requirements

A. All internal appeal and reconsideration requirements shall follow procedures in accordance with R.I. Gen. Laws § 27-18.9-7 and this Part.

B. All review agents shall conform and evidence to the Commissioner the following for the internal appeal of administrative and non-administrative (utilization review) adverse benefit determinations:

1. The review agent shall maintain and make available a written description of its appeal procedures by which the claimant may seek review of determinations not to authorize health care services.

2. The process established by each review agent shall include a reasonable time period within which an appeal must be filed to be considered and that time period shall not be less than one hundred eighty (180) calendar days after receipt of the adverse benefit determination notice.

3. During the appeal, a review agent may utilize a reconsideration process acceptable to the Commissioner in assessing an adverse benefit determination. A reconsideration process for utilization review benefit determinations must also comply with the requirements set forth in § 14.7(C) of this Part.

4. The review agent shall notify the claimant of the reconsideration or internal appeal determination consistent with the form and content requirements set forth in R.I. Gen. Laws § 27-18.9-6(b) and § 14.6(E) of this Part, as appropriate.

C. When a review agent adopts a policy to incorporate a process to perform a reconsideration to assess an adverse benefit determination, it must comply with the following:

1. Perform the reconsideration during the appeals process timelines; and

~~2. Apply the reconsideration process to all adverse benefit determinations made by the review agent; and~~

~~2~~3. The reconsideration process shall be applied in a consistent non-arbitrary manner acceptable to the Commissioner.

D. Prior to a final internal appeal decision, the review agent must:

1. Inform the claimant of the opportunity to review the entire adverse determination and appeal file;

2. Inform the claimant of the opportunity to present evidence and/or additional information as part of the internal appeal process; and

3. Inform the claimant of, and allow the claimant, a reasonable period of time within the appeal notification timeframes, acceptable to the Commissioner in practice and application, to review the entire adverse determination and appeal file and/or to submit additional evidence or information.

E. Pursuant to R.I. Gen. Laws § 27-18.9-7(a)(5), a review agent is only entitled to request and review information or data relevant to the benefit determination and utilization review processes.

F. The review agent shall maintain records of written adverse benefit determinations, reversals of adverse benefit determinations occurring outside of the appeal process, reconsiderations, appeals and their resolution, and shall provide reports to the Office upon request and pursuant to § 14.9 of this Part.

G. For administrative appeals the review agent shall notify, in writing, the claimant of its decision:

1. As soon as practical considering circumstances;

2. In no case later than thirty (30) calendar days after receipt of the request for review of an adverse benefit determination for pre-service claims; and

3. In no case later than sixty (60) days after receipt of the request for review of an adverse benefit determination for post-service claims.

H. For ~~non-urgent or non-emergent~~ utilization review appeals, the review agent shall notify, in writing, the claimant of its decision on the utilization review internal appeal:

1. As soon as practical considering medical circumstances; and

2. Within thirty (30) calendar days after receipt of the request for the review of an adverse benefit determination; or

3. Within forty-five (45) calendar days after receipt of the request for the review of an adverse benefit determination only when the review agent documents that the claimant has requested an extension in order to submit additional information or the carrier substantiates and informs the claimant of the need to obtain additional information in order to make its appeal decision.

I. The review agent shall also provide for an expedited appeal process that takes into consideration medical exigencies according to the following:

1. Urgent and emergent status of a claim shall be determined by the ordering provider or the review agent, and a review agent must honor a determination of urgent or emergent status by an ordering provider; and

2. Adjudication of expedited appeals, including notification to the claimant of its decision on the appeal, not later than seventy-two (72) hours after receipt of the claimant's request for the appeal of an adverse benefit determination.

J. Pursuant to R.I. Gen. Laws § 27-18.9-7(a)(9), benefits for an ongoing course of treatment cannot be reduced or terminated without providing advance notice and an opportunity for advance review. In addition, the review agent or health care entity shall be required to continue coverage pending the outcome of an appeal.

K. For a request for coverage ~~the appeal of a utilization review adverse benefit determination decision for~~ of a drug that is not on the formulary, the review agent shall complete the internal appeal determination and notify the claimant of its determination according the following:

1. No later than seventy-two (72) hours following receipt of the appeal request; or

2. No later than twenty-four (24) hours following the receipt of the appeal request in cases where the beneficiary is suffering from a health condition that may seriously jeopardize the beneficiary's life, health, or ability to regain maximum function, with deference given to any such determination by the ordering provider, or when a beneficiary is undergoing a current course of treatment using a non-formulary drug; and

3. If approved on internal appeal, coverage of the non-formulary drug must be provided for the duration of the prescription, including refills unless expedited pursuant to § 14.7(J)(2), in which case for the duration of the exigency.

L. Pursuant to R.I. Gen. Laws § 27-18.9-7(b)(1), a claimant is deemed to have exhausted the internal appeal process when the review agent conducting utilization review or health care entity fails to strictly adhere to all benefit determination and appeal processes with respect to a claim.

M. Peer reviewers under §14.7 of this Part, who made the adverse benefit determination or reconsideration decisions for the case under appeal or who have participated in the direct care of the beneficiary, may not participate in reviewing the case under appeal.

N. Internal-level appeals decisions of utilization review determinations not to authorize a health care service that had been ordered by a physician, dentist, or other provider, shall be not be made until the review agent's peer reviewer with the same licensure status as typically manages the condition, procedure, treatment, or requested service under discussion has spoken to, or conducted, an equivalent two-way, direct communication with the beneficiary's attending physician, dentist, other professional provider, or other qualified professional provider responsible for the treatment of the beneficiary concerning the services under review.

O. When a utilization review adverse determination is made on internal appeal or reconsideration, including determinations with regard to whether a particular service, treatment, drug, or other item is experimental, investigational or not medically necessary or appropriate, the review agent must adhere to the following:

1. All adverse reconsideration decisions must be made by a peer reviewer;

~~2. The peer reviewer making the appeal decision shall be appropriately trained having the same licensure status as the ordering provider or be a physician or dentist as appropriate;~~

~~3~~2. The peer reviewer making the appeal decision shall be an individual in the same or similar specialty as typically manages the condition;

~~4~~3. The review agent must provide the qualifications of the peer reviewer(s) to the claimant upon request; and

~~5~~4. The review agency's peer reviewers making the reconsideration and internal appeal decisions must document and sign their decisions.

P. The review agent conducting utilization review must ensure that the appropriate peer reviewer making the internal appeal decision is reasonably available to review the case and must conform to the following:

1. Each peer reviewer shall have access to and review all necessary information requested by the agency and/or submitted by the provider(s) and/or claimant; and

2. Each agency shall provide accurate peer reviewer contact information to the ordering provider if requested ~~at the outset of~~ during the utilization review process and upon making an adverse benefit determination ~~as well as promptly upon request~~. In order to ensure direct communication, this

contact information must provide a mechanism for direct communication with the peer reviewer.

3. Peer reviewers making an internal appeal decision shall respond to and reasonably accommodate a provider's request for the equivalent two-way, direct communication required by law prior to the internal level of appeal decision, as well as any additional provider request for a two-way direct communication with a peer reviewer in accordance with R.I. Gen. Laws §§ 27-18.9-7(b)(4) and 27-18.9-7(b)(5) and this Part.

   a. A review agent will have met the requirements of 14.7(P)(3) above, when it has made two reasonable attempts to contact the attending provider.

   b. Repeated violations of this section shall be deemed to be substantial violations pursuant to R.I. Gen. Laws § 27-18.9-13 and § 27-18.9-14 and shall be cause for the imposition of penalties under these sections.

14.8 External Appeal of Non-Administrative Benefit Determinations Requirements

A. In the cases where the utilization review adverse benefit determination or the final internal level of appeal to reverse a utilization review adverse benefit determination is unsuccessful, the health care entity or review agent shall provide for an external appeal by an independent review organization (IRO) approved by the Commissioner and ensure that the external appeal complies with all applicable laws, regulations, and the Office's instructions.

B. In order to seek an external appeal;

   1. The claimant must have exhausted the internal appeal process; and

   2. The claimant is deemed to have exhausted the internal appeal process when the review agent or health care entity fails to strictly adhere to all benefit determination and appeal processes with respect to a claim; or

   3. The claimant has applied for expedited external review at the same time as applying for expedited internal review.

C. R.I. Gen. Laws § 27-18.9-8(a)(3), a claimant shall have at least four (4) months after receipt of a notice of the decision on a final internal appeal to request an external appeal by an IRO.

D. Health care entities and review agent must use a rotational IRO registry process specified by the Commissioner.

E. Pursuant to R.I. Gen. Laws § 27-18.9-8(a)(5), a claimant requesting an external appeal may be charged no more than a twenty-five dollar ($25.00) external appeal fee by the review agent. The external appeal fee, if charged, must be refunded to the claimant if the adverse benefit determination is reversed through external review. The external appeal fee must be waived if payment of the fee would impose an undue financial hardship on the beneficiary. In addition, the annual limit on external appeal fees for any beneficiary within a single plan year (in the individual market, within a policy year) must not exceed seventy-five dollars ($75.00).

F. A claimant requesting an external appeal of an excepted benefit as defined in 42 U.S.C. § 300gg-91(c), may be charged no more than a ~~fifty~~ one-hundred dollars ($105~~0~~.00) external appeal fee by the review agent. The external appeal fee, if charged, must be refunded to the claimant if the adverse benefit determination is reversed through external review. The external appeal fee must be waived if payment of the fee would impose an undue financial hardship on the beneficiary. In addition, the annual limit on external appeal fees for any beneficiary within a single plan year (in the individual market, within a policy year) must not exceed ~~one~~three-hundred ~~and fifty~~ dollars ($~~150~~300.00).

G. Pursuant to R.I. Gen. Laws § 27-18.9-8(a)(6), the IRO and/or the review agent and/or the health care entity may not impose a minimum dollar amount of a claim for a claim to be eligible for external review by an IRO.

H. Pursuant to R.I. Gen. Laws § 27-18.9-8(a)(7), the decision of the external appeal by the IRO shall be binding on the health care entity and/or review agent; however, any person who is aggrieved by a final decision of the external appeal agency is entitled to judicial review in a court of competent jurisdiction.

I. Pursuant to R.I. Gen. Laws § 27-18.9-8(a)(8), the health care entity must provide benefits (including making payment on the claim) pursuant to an external review decision without delay.

J. Pursuant to R.I. Gen. Laws § 27-18.9-8(a)(9), the Commissioner shall determine the process and criteria for designation, operation, policy, oversight, and termination of designation as an IRO. The IRO shall not be required to be certified under the Act or these regulations for activities conducted pursuant to its designation.

K. The health care entity and the review agent must ensure that the external appeal process shall include, but not be limited to, the following characteristics:

1. ~~The claimant must receive from the review agent,~~ W~~w~~ithin at least five (5) business days of the request for an external appeal, a notice must be received by the claimant that their request has been forwarded to the independent review organization (IRO). The notice shall include a

description of the process for the claimant to submit additional information to the IRO within five (5) business days of receipt of this notification.

2. Pursuant to R.I. Gen. Laws § 27-18.9-8(b)(2), the IRO must notice the claimant of its external appeal decision to uphold or overturn the review agency decision:

a. No more than ten (10) calendar days from receipt of all the information necessary to complete the external review and no more than forty-five (45) calendar days after the receipt of the request for external review; and

b. In the event of an expedited external appeal by the IRO for urgent or emergent health care services, as expeditiously as possible considering exigencies and no more than seventy-two (72) hours after the receipt of the request for the external appeal by the IRO.

L. When a utilization review determination is made on external appeal, including determinations with regard to whether a particular service, treatment, drug, or other item is experimental, investigational or not medically necessary or appropriate, the IRO must adhere to the following:

1. All adverse ~~reconsideration~~ external appeal decisions must be made by a peer reviewer;

2. The external appeal reviewer making the external appeal decision shall be appropriately trained having the same licensure status as the ordering provider or be a physician or dentist as appropriate;

3. The external appeal reviewer making the external appeal decision shall be an individual in the same or similar specialty as typically manages the condition;

4. The IRO must provide the qualifications of the external appeal reviewer(s) to the claimant upon request; and

5. The external appeal reviewers making the external appeal decisions must document and sign their decisions.

M. For an external appeal of an internal appeal decision of a non-formulary drug, the health care entity and the review agent must ensure that the IRO completes the external appeal determination and notifies the claimant of its determination:

1. No later than seventy-two (72) hours following receipt of the external appeal request; or

2. If the original request or appeal was an expedited request, as soon as possible taking into account exigencies and no later than twenty-four (24) hours following the receipt of the external appeal request; and

3. If approved on external appeal, coverage of the non-formulary drug must be provided for the duration of the prescription, including refills, unless expedited then for the duration of the exigencies.

N. A health care entity and review agent must ensure that the IRO adheres to the external appeal decision notifications in accordance with R.I. Gen. Laws § 27-18.9-8(c) and this Part.

14.9 Reporting

A. Each agency shall compile and maintain reports in form and content consistent with instructions issued as a bulletin by the Office for that purpose and these reports shall:

1. Include but not be limited to a report that includes all utilization review benefit determinations made by the agency and its delegates (if applicable), broken down by ~~procedural~~ categories set forth by the Office, which categories may change from time to time at the discretion of the Commissioner; and

2. Be filed with the Office according to the Office's instructions, no more frequently than quarterly.

B. Each agency shall promptly comply with periodic requests by the Commissioner and/or the Office for information, data and/or reports requested for the purpose of determining compliance with the Act, this Part, and any applicable federal laws or regulations relating to the Act.

14.10 Waiver of Requirements

A. The Office shall waive the requirements of the Act or this Part only when the Commissioner has determined a conflict exists with those activities of a review agent that are conducted pursuant to contracts with the state or the federal government or those activities under other state or federal jurisdictions.

B. The Office shall waive de minimus activity as determined by the Commissioner.

14.11 Variance Requirements

Statutory variances are governed by R.I. Gen. Laws § 27-18.9-12.

14.12 Denial, Suspension, or Revocation of Certification

Denial, suspension, or revocation or certification is governed by R.I. Gen. Laws § 27-18.9-13.

14.13 Penalties and Enforcement

Penalties and enforcement are governed by R.I. Gen. Laws § 27-18.9-14.

14.14 Severability

If any section, clause, provision or application of the Act or this Part shall be held either unconstitutional or ineffective in whole or in part, to the extent that it is not unconstitutional or ineffective, it shall be valid and effective, and no other section, clause, provision or application shall on account thereof be termed invalid or ineffective.