## REPORT AND RECOMMENDATIONS ON WASHINGTON STATE'S INDEPENDENT REVIEW SYSTEM



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#### I. Introduction

This report discusses Washington's 14-year-old system for collecting, analyzing, and making publicly available decisions by Independent Review Organizations (IROs), and provides recommendations to improve the system for consumers and regulators. Our proposals address issues of transparency and consolidation of authority and are not dramatic shifts. These suggestions take into account the limited resources available to regulators and the IRO projects currently in progress.

IROs review health care insurance claim denials after an insured (plan enrollee) has exhausted the insurer's internal appeal process. The IRO process thus adjudicates claims disputes, as distinct from providing or managing health care services.

Because medical treatments and standards evolve, it is important to have an insurance appeal system that considers developments in medicine as part of claims decisions. The IRO process can serve to correct trends in insurer decisions, such as denials of claims as not "medically necessary" or not "experimental/investigational." Regulators can then review these trends as part of their oversight responsibilities.

To date," in Washington, no IRO decisions have been systematically collected or trends analyzed, records are practically inaccessible, and quality of the decisions varies widely. The lack of a usable system has precluded consumers from finding and using IRO decisions in their efforts to appeal insurer denials, and has hampered effective enforcement and regulation by OIC.

By contrast, California regulators, iii in their parallel system of "Independent Medical Reviews" (IMRs), established searchable databases at the outset of their program in 2001. These databases have allowed California to extensively study insurer trends and enforce compliance with the law. A comprehensive study of California's experience demonstrates, through analysis of the data collected,<sup>2</sup> that IMRs actually influence insurers to grant claims as medical treatments and procedures evolve from experimental to medically necessary. See Section V.A. For example, California has been able to investigate whether carriers routinely deny treatment for a condition (such as a type of cancer, or autism) as experimental or investigational, even when studies have shown the treatment to be medically necessary. The regulators have then used the results of this research to correct improper denials.

In Washington, an effort to create more transparency is already underway: OIC is developing a searchable database of IRO decisions to be launched in 2015-16.3 The OIC database is intended to allow consumers, usually unrepresented in this process, to find decisions like their own, in turn helping them mount effective external appeals. The database will also facilitate regulatory oversight and enforcement. A well-designed database could significantly benefit consumers and OIC in the following ways:

<sup>&</sup>lt;sup>i</sup> The Office of Insurance Commissioner (OIC) and Department of Health (DOH).

Washington's system IRO began in 2000.

iii California Department of Managed Health Care (DMHC) and California Department of Insurance (CDI).

- The collection of information about IRO decisions would be more uniform and accessible.
- A person appealing a benefit denial would be able to determine whether there are any
  previous IRO decisions overturning similar claim denials. Making this information
  available should help level the playing field by enabling consumers to effectively prepare
  and present their appeals for adjudication by an impartial decisionmaker.
- The decisions can contain required elements, ensuring higher quality.
- Data and trends from the decisions would give OIC the ability to enforce and regulate carriers when patterns of improper denials emerge.

Washington's database is ultimately expected to be as useful as California's. But since Washington does not have a history of meaningful data collection and public access to IRO decisions, this may take time. Amendments to the statutes and regulations should shorten this transition.

As recognized by OIC in developing the database, one first step in improving Washington's system is to provide the public with access to other IRO decisions. In this regard, we propose that OIC collect IRO decisions directly from the carriers, who would first redact personal health information, and OIC, after confirming that confidential material is redacted, would post the redacted IRO decisions on the public database.

In addition, we support consolidating all aspects of the IRO process in OIC rather than the current system where DOH certifies IROs, collects annual summary reports, and has audit and investigative authority. Legislative changes could accomplish these goals, including consolidation of the IRO system in OIC, requiring better reporting and production of IRO reports to the regulator, and setting up the database.

Those involved in the IRO program agree that an improved, transparent system is long overdue. As one advocate said, when told about OIC's database, "A searchable database sounds too good to be true." The database, along with other reform, would have great value for patients, particularly the majority who must represent themselves in the appeals process.

#### **II. Summary of Recommendations**

Our recommendations, summarized here and discussed in more detail below, would result in consolidation of the IRO program in OIC, a searchable public database of IRO decisions, improved reporting requirements, consistent quality of reports, and better compliance and enforcement.

#### A. Consolidate IRO reporting, data collection, and regulation in OIC

RCW 48.43.535 (providing OIC with authority over IROs, primarily managing a rotational registry) should be revised to transfer to OIC authority currently in DOH (RCW 43.70.235 and WAC Chapter 246-305). This consolidation would ensure appropriate oversight and analysis of the information collected from IROs.

Carriers should be required to produce redacted copies of IRO decisions to OIC, and OIC should make redacted copies of these decisions publicly available. IROs would submit an annual statistical summary report to OIC, instead of to DOH as is currently required.

As noted below, the statute should be amended to list elements IROs must include in their decisions, to improve quality and consistency. The statute should also provide that IROs conduct annual self-assessments of their compliance with the statutory and regulatory requirements.

Similar changes should also be made to OIC's bill establishing independent reviews for long-term care insurance. iv

## B. Continue developing a strong, transparent independent review decision database managed by OIC

Our recommendations regarding OIC's database project stem from an analysis of Washington's current system and a comparison to California's IMR system.

OIC's searchable database of redacted IRO decisions should include sortable fields such as health condition, procedure, carrier name, and others set forth below, to provide consumers and regulators the information they need. Searchability by carrier, which OIC has said they plan to include, is particularly important. This will allow a consumer to ascertain how IROs have addressed similar decisions with a particular carrier, and OIC can identify insurers that need more monitoring or enforcement.

The database will integrate into OIC's current web search system ("SIMBA"). OIC intends this tool to promote consumer searches as well as OIC enforcement. We agree with this approach and wish to ensure that it is easy for consumers to use.

#### C. Improve the quality of IRO decision reporting

A database is only as good as the information it contains. Currently, IRO decisions vary in content and are not standardized, despite regulations requiring certain content. In conjunction with developing the new database, OIC should create a form for IROs to use in issuing decisions. The contents of the form should reflect statutory or regulatory requirements and should be accompanied by instructions requiring more detail in IRO decisions.

In addition, our review of IRO decisions raised concerns that medical/clinical reviewers issuing IRO decisions may not be properly trained to interpret and apply health insurance policy provisions, such as those used to determine medical necessity. The OIC database should track the assignment of qualified decisionmakers for contractual issues, including "contract specialists", WAC 246-305-040(4), (5);<sup>4</sup> -010(9),<sup>5</sup> by requiring that IROs (a) identify any appeal involving a contractual issue, and (b) identify the qualifications of the reviewer for such an issue.

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House Bill 1066, pending in the 2015 Washington Legislature as of this writing. This could be done by incorporating long term care reviews into the amended RCW 48.43.535.

<sup>&</sup>lt;sup>v</sup> See Appendix B: Comparison of Washington and California's requirements for independent review decisions.

If OIC finds medical expertise to be necessary in managing the IRO system, persons with such expertise could be retained on a consultative basis when auditing IROs or considering enforcement.

#### III. Washington's Independent Review System and Related Agency Authority

Washington enacted an independent review system as part of its Health Care Patient Bill of Rights in 2000.<sup>6</sup> This system provides that "consumers who have been denied coverage or payment by the health insurance carrier have a right to an impartial, external review of their case."

#### A. DOH authority

Under the current system, DOH certifies IROs (WAC 246-305-020 to -040; -080 to -090) and has established a procedure for independent reviews (WAC 246-305-050, -051, -060). Among other rules, DOH regulations require IROs to have quality assurance and training programs, and IROs must maintain case logs and case files with complete documentation. WAC 246-305-070(3), (4). IROs are to submit an annual statistical report to DOH on DOH's form, summarizing reviews conducted, including "volumes," types of cases, compliance with timelines, and other items. WAC 246-305-090(5).

The above functions do not necessarily require the regulator to have medical expertise, and in fact, are more appropriately done by those with an understanding of insurance policies and contract interpretation.

We did not investigate whether IROs are complying with these requirements or what DOH does to monitor or enforce compliance. We understand, however, that the documents we reviewed for this report in response to a public records request<sup>9</sup> were the first known collection of IRO decisions by DOH and the first review by OIC since the program began in 2000.

#### **B. OIC authority**

OIC maintains a rotational registry of IROs from which carriers select reviewing IROs to accept requests independent review. RCW 48.43.535(10); WAC 284-43-550(2). See also WAC 284-43-630 (instructions to carriers regarding independent review). OIC can request records from IROs. RCW 48.43.535(10). IROs may (but are currently not required to) notify OIC if they find "a pattern of substandard or egregious conduct by a carrier." RCW 48.43.535(11). 12

Separate from OIC's responsibilities related to IROs, note that OIC has the authority to hold hearings, RCW Chapter 48.04, and issue "declaratory orders" which have "the same status as any other order" entered by the agency in an adjudicative proceeding, and are limited to the particular facts and parties, RCW 34.05.240.<sup>13</sup> The Washington Insurance Commissioner "can enforce decisions, and can issue declaratory orders in contested cases. RCW 48.02.080[.]" \*Credit Gen. Ins. Co. v. Zewdu\_ 82 Wn.App. 620, 626-27 (1996). See also RCW 48.02.060 (general powers and duties).

OIC can also issue a memo to insurers emphasizing that repeated IRO reversals of an insurer's designation of a claim as experimental are in bad faith and a violation of Washington law. *See* RCW 48.01.030 (insurers have a duty of good faith); RCW 19.86.020, RCW 19.96.090

(Washington Consumer Protection Act). This was done in California, as described below. *See* Section VI.B.

#### IV. Analysis of Washington IRO System

#### A. Introduction

For this report, we reviewed over 2,000 pages of records produced by DOH in response to a public records act request. Almost all the records were IRO decisions made in 2013 by eight IRO companies. *See* Endnote 9. These records revealed the following problems with the current IRO system.

#### B. Inadequate reporting, data collection, and accessibility

#### 1. Annual summaries

WAC 246-305-090(5) requires all certified IROs to:

[s]ubmit an annual statistical report [to DOH] with the department on a form specified by the department summarizing reviews conducted. The report shall include, but may not be limited to, volumes, types of cases, compliance with timelines for expedited and nonexpedited cases, determinations, number and nature of complaints, and compliance with the conflict of interest requirements described in WAC 246-305-030. vi

The IRO annual summaries we reviewed varied in quality. Moreover, the summaries have not been provided to DOH in a way that would meaningfully allow claimants to access and use successful IRO decisions. The database and revised standard form being developed should correct these issues.

Before the current IRO project and database development, OIC did not receive copies of the annual reports or the actual IRO decisions issued, not even for use in monitoring systemic problems, even though RCW 48.43.535(11) authorizes (but does not require) IROs to notify OIC of trends in the reviews.

The annual summary and other reporting requirements could be placed in the insurance statute and provide that IROs must send annual summary reports directly to OIC on a revised form developed by OIC.

RCW 48.43.535(12)(a) currently gives OIC authority to promulgate rules for other changes: "The commissioner shall adopt rules to implement this section after considering relevant standards adopted by national managed care accreditation organizations and the national association of insurance commissioners." <sup>15</sup>

To date, only the IROs and the carriers themselves have had the data and statistics needed to make the IRO system effective for all players. The proposed consolidation of authority in OIC and new reporting requirements should help remedy this imbalance.

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vi Statutory authority: RCW 43.70.235, RCW 48.43.535.

#### 2. IRO decisions not provided to OIC

Currently, OIC does not automatically receive IRO decisions but must request them from DOH, which has not been collecting them in the first place. Because OIC needs the decisions for the database to effectively track trends and regulate IROs, OIC should collect IRO decisions directly.

#### C. Quality of IRO decisions is uneven

OIC has acknowledged that the quality of the decisions varies and that better reporting requirements are necessary. Our review and comments from others familiar with the IRO process confirm that IRO decisions are inconsistent in format and information.

In the records we reviewed from 2013, some reports did not identify the condition, disputed treatment, or specific analysis for overturning the insurer's denial, but were simply one-page forms with very limited information.<sup>16</sup>

One reason the quality of decisions is uneven is that the applicable regulations have minimal requirements for IRO reports, and different elements for medical necessity decisions and experimental/investigational ones (see Appendix B). In addition, it appears that IROs have their own dissimilar forms or standards for written decisions.

In California, the basic requirements for IMR decisions are the same for medical necessity and experimental/investigational, except for a different list of "findings" for each (see Appendix B), whereas in Washington, the requirements for experimental/investigational are quite detailed as compared to those for a medical necessity decision. Compare WAC 246-305-051 (experimental/investigational) with -050 (medical necessity). WAC 246-305-060 provides general criteria and considerations for IRO decisions, but does not state what must be in the written report.

We propose that decisions include the criteria identified below, combining current Washington laws and regulations with elements in California's laws, to include more information. This will both improve the quality of decisions and aid in making the database more complete and useful.

To accomplish that goal, OIC intends to develop a standardized form. OIC should also provide instructions to IROs to ensure a more uniform, complete decision format, and then enforce compliance with this format.

The suggested elements for reports are:

- The enrollee's medical condition;
- A general description of the reason for the request for independent review;
- The date the review was requested;
- The date the review was conducted;
- The date of the IRO's decision;
- The relevant documents in the record;
- The principal reason or reasons for the IRO's decision; and
- The rationale for the IRO's decision; specifically including:

- The relevant findings to support the determination, the written opinion of each clinical reviewer, whether the recommended or requested health care service or treatment should be covered, the rationale for each reviewer's recommendation, including its clinical basis unless the decision is wholly based on application of coverage provisions;
- Documentation of the basis for the determination including references to supporting evidence, and if applicable, the rationale for any interpretation regarding the application of health plan coverage provisions;
- If the determination overrides the health plan's medical necessity or appropriateness standards, the rationale shall document why the health plan's standards are unreasonable or inconsistent with sound, evidence-based medical practice.
- The written report shall include the qualifications of reviewers but shall not disclose their identity.

#### D. No practical availability of records

In Washington, the IRO decisions themselves are difficult for consumers to obtain. It took four months for DOH to produce IRO records to us through a public records act request. The upcoming database will make IRO decisions searchable but they must also be more readily available to the public in redacted form, as provided in our proposal.

We understand that adequately redacting personal health information is a significant concern when specific information is placed on the internet; however, this does not present an insurmountable obstacle. The current volume of IROs is fairly low. Decisions could be sorted for matters like rare diagnoses, and safeguards could be developed for these. Use of the standardized form should simplify the sorting and redaction process.

#### V. California's IMR System – Promising Practices

#### A. Overview

. . . . .

In California, IMRs are gathered primarily by the California Department of Managed Health Care (DMHC, which regulates coverage for over 21 million Californians), with far fewer governed by the California Department of Insurance (CDI, which regulates coverage for fewer than two million). The number of plan enrollees in Washington subject to OIC carrier regulation is obviously much smaller.<sup>17</sup>

Unlike Washington, in California, because IMR is available for only certain types of cases, requests for independent review come to the regulators, who then review them to determine if they are eligible.<sup>18</sup> At DMHC, review of complaints is done by a team consisting of an attorney, nurse, and program analyst. At CDI, the team is comprised of insurance compliance officers and CDI management. *Ten Years Report*, at 8. In California, independent review of coverage questions is by the regulators. By contrast, in Washington, as noted, regulations require

vii This list combines elements in WAC 246-305-050(5) (documentation of IRO decisions), -051 (additional requirements for experimental or investigational reviews), and Cal. Health & Safety Code §1374.33(c) – (h) (eff. July 1, 2015).

"contract specialists" to address coverage questions. The IRO determines when a matter should be assigned to a contract specialist. VIII

The California system has searchable databases, an enforcement mechanism, and other promising practices that could be adapted for use in Washington.

#### B. California's databases

For years, since the beginning of the IMR program, DMHC and CDI have provided online searchable databases for IMR cases, and made IMR data available to the public. *Ten Years Report*, at 25. The DMHC searchable database of "all IMR decisions since the program began" in 2001 is at <a href="http://wpso.dmhc.ca.gov/imr/">http://wpso.dmhc.ca.gov/imr/</a>. Searchable fields presently include:

- type (that is, experimental/investigational, medically necessary, or urgent care);
- determination (any determination, overturned, or upheld);
- year range;
- gender;
- diagnosis category (e.g., autism spectrum, chronic pain, cancer, morbid obesity, etc.); and diagnosis subcategory (e.g., hypertension, etc.);
- treatment category (*e.g.*, acute medical services—inpatient, home health services, etc.) and treatment subcategory;
- keyword search.<sup>19</sup>

When a user successfully searches the DMHC database, the IMR's "findings" can be viewed.

Additional fields are required by California's amended laws, effective July 1, 2015. It is not possible to search California's databases by insurer. After July 1, 2015, however, the consolidated database of CDI and DMHC reviews must include the annual rate of IMR cases by plan, and the number, type, and resolution of IMR cases by plan. Cal. Health & Safety Code §§ 1374.33(h)(2)(B), (C).

In addition, CDI currently has an Interactive IMR Statistics webpage where cases can be searched diagnosis, diagnosis subcategory, treatment, treatment subcategory, year, outcome, type, keyword search.<sup>20</sup>

These databases allow insureds to use prior decisions in their own appeals or independent review requests. Moreover, the California regulators employ the database to monitor for systemic issues. While this dynamic may seem obvious, The *Ten Years Report* confirms the importance of the database to the IMR program:

#### IMR Influence on Health Plan Decision-Making

IMR cases often involve new and emerging types of treatments or services. This review of the detailed DMHC case descriptions revealed that IMR cases cluster around situations where identifying the best treatment for a particular disease is an unsettled issue in the medical community. Discussion between this paper's authors and health plan medical staff confirmed that areas where the

As discussed, there is some concern that IROs are having clinical/medical reviewers decide contract questions.

The OIC database, by tracking which reviewers are deciding which issues, should help to address this concern.

state of medical knowledge is still evolving tend to drive more requests for IMRs. Similarly, IMRs for emerging treatments decline as medical knowledge and practice evolve and there is greater agreement about those treatments among the medical and health plan communities.

Ten Years Report, at 15 (emphasis added).<sup>21</sup>

#### C. California regulatory authority compared to Washington's

DMHC is required to "perform an annual audit of independent medical review cases for the dual purposes of education and the opportunity to determine if any investigative or enforcement actions should be undertaken by the department, particularly if a plan repeatedly fails to act promptly and reasonably to resolve grievances associated with a delay, denial, or modification of medically necessary health care services when the obligation of the plan to provide those health care services to enrollees or subscribers is reasonably clear." Cal. Health & Safety Code § 1374.34(e). This provision is used frequently in California to identify and resolve systemic issues.

Moreover, California's Administrative Procedure Act explicitly gives regulators authority to issue precedential decisions. This authority governs all licensed carriers and the IMR process.<sup>22</sup>

Washington's Administrative Procedure Act, RCW Chapter 34.05, does not include a counterpart to California's annual audit requirement or its precedential decision statute but, as previously noted, the OIC has general authority to hold hearings and issue declaratory orders.

#### D. California legislative reform

In California, the *Ten Years Report* led the Legislature to enact SB 1410 in 2012,<sup>23</sup> effective July 1, 2015, adopting the Report's recommendations to make "administrative improvements ... to more effectively deliver the promise of a credible, transparent, and effective IMR program."<sup>24</sup> SB 1410 requires CDI and DMHC "to collaborate on a common, free, searchable database of IMR cases that will include information beyond what either department is currently providing, such as patient race, ethnicity, and primary language spoken." The bill also addressed "the concern that reviewers are not always appropriately qualified by requiring reviewer qualifications to be reported in the database and by elevating required reviewer expertise to the level advocated by federal law."<sup>25</sup> See amended Cal. Health & Safety Code § 1374.30(g), (h); Cal. Ins. Code § 10169.3(1)(g), (h)).<sup>26</sup>

#### VI. Use of IRO decisions: case illustrations

#### A. Enforcing insurer compliance: examples from California

The *Ten Years Report* provides two examples of the effect of a functional independent review program.<sup>27</sup> In California, IMRs involving bariatric surgery grew rapidly from 2001-03, with a parallel increase in IMR results overturning health plan denials. After 2003, the number of IMRs for bariatric surgery declined and remained steady from 2005 on. The peak of IMRs involving bariatric surgery "most likely reflected unsettled medical practice and evolving health plan internal policies regarding which patients should be candidates for bariatric surgery". *Id.* "The steep increase in IMR cases drove health plans to look more closely at the bariatric procedures

.... Ultimately, the combination of IMR findings, additional research, and increased regulatory scrutiny served to inform the medical dialogue and health plan decision-making." *Id.* at 15-16.

Similarly, statistics on Botox treatment for migraines show that unsettled or inadequate medical evidence and practice caused an increase in IMRs, which then declined as a medical consensus developed. *Id.* at 17.

These results suggest that when scientific evidence and medical practice are evolving, IMR reviewer decisions are inconsistent. The inconsistency is complicated by the fact that in the past, IMR decisions processed identical treatments differently, as either experimental or medical necessity. This has been true for all conditions. *Id.* 17-18.

Another example of a regulator using IMRs to enforce insurer compliance is CDI's 2011 decision bulletin regarding treatment for autism. CDI noticed that IMRs repeatedly reversed health insurer decisions excluding coverage for Applied Behavioral Analysis (ABA) therapy for Autism Spectrum Disorder (ASD) as experimental. Based on that trend, the CDI issued a memo to carriers warning that excluding ABA therapy as experimental, when IMR decisions had consistently found they were not, violated the carrier's duty of good faith towards its insureds.<sup>28</sup> The Oregon Insurance Division issued a similar bulletin in the fall of 2014.<sup>29</sup>

#### B. IRO decisions as an aid to consumers and regulators

The records we received contain a successful IRO decision overturning Premera Blue Cross's decision to deny benefits as experimental/investigational for a proposed cytoreductive surgery on a patient with stage 4 colon cancer, just days before the surgery was to occur. Initially, during two levels of Premera's internal appeal process, Premera maintained that coverage was denied because the treatment was experimental/investigational under its policy, though the treating surgeon had performed the procedure on other Premera insureds with the same disease and Premera had allowed benefits.

The enrollee ultimately prevailed, but only because her family found an advocate who had previously succeeded in reversing denials for Premera enrollees involving the same procedure under the same policy, both on internal appeals and at the IRO level. Through this advocate, the enrollee submitted relevant redacted past decisions, and won. Meanwhile, the surgery was delayed for months (August-November 2013).

After the IRO overturned Premera's denial, the patient's family filed a complaint with OIC. OIC requested that Premera cease classifying the procedure as experimental/investigational because the IRO reviewer (a nationally-recognized surgical oncologist) stated the treatment "would not be considered by the general medical community to be experimental/investigational". OIC also pointed out that reclassifying the treatment would not require Premera to pay for any insured requesting it; Premera would still be able to conduct a medical necessity review for each consumer's individual situation. (Nov. 25, 2013 Letter, OIC to Premera.)

Surprisingly, Premera refused OIC's request to reclassify. (Dec. 18, 2013 Letter, Premera to OIC). OIC then closed the complaint, stating there was nothing more they could do.

To the contrary, OIC has the authority to do what the California Department of Insurance did when they encountered a pattern of carriers denying ABA therapy for autism: OIC could inform insurers that repeated IRO reversals of an insurer's designation of a claim as experimental demonstrates bad faith and a violation of Washington law. *See* RCW 48.01.030; RCW 19.86.020, RCW 19.96.090.

Given that at least one insurer refused to comply with OIC's attempts at enforcement in this manner, OIC should be able to clarify its authority over carriers and IROs by bulletins, memoranda, regulations, or precedential decisions.

#### C. An effective IRO system can prevent costly litigation

An effective IRO system could save time, effort, and costs involved in litigation, for example, regarding improper blanket exclusions or patterns of benefit denials.

After years of litigation to change insurers' blanket exclusions for ABA therapy for autism, in October 2014, the Washington Supreme Court held that insurers may not use blanket exclusions to deny treatment for mental health conditions that are medically necessary, specifically including ABA for autism. *O.S.T. v. Regence BlueShield,* No. 88940-8 (Oct. 9, 2014) (en banc). Regence then settled with plaintiffs in that class action and a federal class action, changing treatment limitations or caps on medically necessary neurodevelopmental therapy services and specifying terms and conditions for covering medically necessary ABA therapy to treat autistic insureds.

Also as a result of this decision, OIC issued a bulletin to all health carriers announcing enforcement decisions such as: OIC will review blanket exclusions in filings for the 2015 plan year to ensure that medically necessary mental health services are not inappropriately excluded; OIC will order carriers to change noncompliant provisions; and OIC provided clear instructions to insurers regarding current claims.

The robust IRO system changes in progress now and proposed here could help resolve similar issues without the need for costly, lengthy lawsuits.

#### VII. Recommendations

#### A. Consolidate responsibility in OIC

To ensure appropriate oversight and analysis of the information collected from IROs, statutes or regulations should place the responsibility for IRO reporting, data collection, and regulation of the IROs with OIC. The entire IRO system would be aided by consolidation of responsibility in OIC and improvements in how decisions are reported.

As noted, IROs involve claims dispute management rather than regulation of health services. DOH, which currently handles IRO reporting, is not otherwise responsible for regulating health insurance and is not funded to do so. It makes more sense to have OIC, the agency responsible for regulating carriers, accept annual summaries and decisions, so that it can set standards for their content and quality. OIC has staff who are trained and experienced in interpreting and applying policy provisions in a manner consistent with the insurance laws and regulations. OIC staff also are capable of and charged with analyzing trends in the insurance industry. Moreover, OIC standards for publicly available decisions would aid consumers in their appeals.

OIC currently has explicit authority to make rules regarding the IRO process, as well as provisions requiring IROs to maintain written records of their decisions and to "make them available upon request to the Commissioner." RCW 48.43.535(10-12).

Specifically, RCW 48.43.535 should be amended to require IROs to report to OIC instead of to DOH. *See* WAC 246-305-090 (*e.g.*, requiring annual self-assessments and annual statistical report). In addition, all health carriers should be required to produce to OIC redacted copies of all IRO decisions, which OIC would make publicly available. The statute should be amended to list elements IROs must include in their decisions (discussed below), to improve quality and consistency, and should provide that IROs conduct annual self-assessments of their compliance with the statutory and regulatory requirements.

With OIC as IRO regulator, IRO annual summaries and decisions can be reviewed as an important part of OIC's carrier oversight. While we recognize that resources are limited, the current volume of IROs is low enough that this program transition should not overwhelm OIC.

<u>Interagency Agreement</u>: OIC and DOH have been working on an interagency agreement to coordinate quality assurance for IRO reports. While this agreement will undoubtedly help, if OIC is to be the lead agency, this should be clear in statute.

If consolidation in OIC is not possible to accomplish by statute, then the agencies should immediately explore an alternative: DOH could delegate many of its IRO functions to OIC through the interagency agreement. This might accomplish much of the same result as the statutory and regulatory changes suggested.

## B. Continue development of a searchable, accessible database of pertinent information, with IRO decisions publicly available

OIC should continue to develop and manage a searchable, accessible database so consumers and regulators can identify the information they need.

Based on our analysis of Washington's current system and comparison to California's IMR system, the database should have the following functionality:

- Sortable fields including health condition, procedure, carrier name, and others recommended below.
- Ability to search by carrier, so there is public information on which carriers are doing what, and to demonstrate whether carriers need more monitoring or enforcement.

The regulator must redact all Personal Health Information included in the decision before placing it in the database.

As planned, the database will integrate into OIC's existing web search system (SIMBA). We agree with this approach as long as it is easy for consumers to use.

The first step ("Phase 1") (December 2014) involved creating a system for matching the information OIC receives from carriers about each IRO assigned with the determinations DOH has obtained from the IROs. OIC worked with DOH to create a template that performs this matching function. OIC intends the template in development to be a tool to promote consumer searches as well as OIC enforcement. While this will provide some information, it must be improved in order to be fully searchable.

As California's experience demonstrates, disclosure of IRO decisions is especially important where the insurer relies on a blanket exclusion (like the experimental/investigational, custodial or "maintenance care" exclusions) rather than an individualized medical necessity determination. *See* Commissioner Kreidler's October 20, 2014 Bulletin to health carriers (announcing review of blanket exclusions; medically necessary mental health services may no longer be inappropriately excluded). When an IRO reverses an insurer's denial based on a blanket exclusion, that decision clearly applies in other situations involving the exclusion.

For these reasons, carriers and IROs should be required to report the following items to OIC for the database. Items (1)-(2), (4)-(10), (12)-(14) are required in California; items (3) and (11) are our additions. Item (3) requires searchability by carrier and Item (11) is based on the need to monitor access to the IRO process to ensure it is equally accessible to Limited English Proficient (LEP) individuals. Carriers should report Items (1)-(11) to OIC, and IROs should report Items (12)-(14) on the annual statistical summary report form to be developed by OIC.

#### Carrier reporting requirements for database:

- (1) Enrollee demographic profile information, including age and gender.
- (2) Enrollee diagnosis and disputed health care service.
- (3) Name of the carrier.
- (4) Whether the independent review was for medically necessary services (RCW 48.43.535(6)) or for experimental or investigational treatment (RCW 48.43.535(7)(b)).
- (5) Whether the independent review was standard or expedited.

- (6) Length of time from the IRO's receipt of a request for review and the supporting documentation, until the IRO renders a determination to the enrollee in writing.
- (7) Credentials and qualifications of the reviewer or reviewers.
- (8) The nature of the criteria that the reviewer(s) used to make the case decision.
- (9) The final result of the determination, with the date the determination was made.
- (10) A detailed case summary that includes the specific standards, criteria, and medical and scientific evidence, if any, that led to the case decision.
- (11) If the appellant is Limited English Proficient, were all IRO notices and decisions translated and provided to them in a timely manner?

#### IRO reporting requirements for database:

- (12) The annual rate of independent review cases by carrier.
- (13) The number, type, and resolution of independent review cases by carrier.
- (14) The number, type, and resolution of independent review cases by ethnicity, race, and primary language spoken.

In addition, as in California, OIC should include the annual rate of independent review among the total enrolled population.

#### C. Improve the quality of IRO decision reporting

A database is only as good as the information it contains. Currently, IRO decisions vary in content and are not standardized, despite DOH regulations requiring certain contents. *See* Appendix B. Some decisions we reviewed did not all include sufficient information to understand the issue or basis for the decision.

IRO decisions must follow the explicit requirements of the governing statutes and regulations; in fact, WAC 246-305-090 explicitly says so: "A certified IRO shall: (1) Comply with the provisions of RCW 43.70.235, 48.43.535(5), and this chapter ...." This requirement should be set forth in the amendment to the statute.

We support OIC development of a form for IROs to use. A form that includes all the required elements for the database (as well as for the decision) will improve compliance with existing standards and ensure uniformity of IRO decisions.

Together, the form and statutes or regulations setting forth the required elements for IRO decisions will make the database more complete and useful. Further, OIC should provide instructions to IROs to ensure a more uniform, complete decision format, and then enforce compliance with this format.

In Washington's IRO system, reviewers are generally physicians. Despite the DOH regulations governing who performs reviews of medical versus contractual issues (WAC 246-305-040), there are questions as to whether medical reviewers are properly interpreting and applying policy provisions in determining medical necessity. Should they instead be consulting "contract specialists" who are trained and competent in the relevant legal concepts?

Unlike the review for eligibility of an IMR in California, in Washington, the carrier refers an external appeal directly to an IRO using OIC's rotational registry. The IRO is then responsible for independent review of both medical and coverage questions. DOH regulations provide that medical reviewers can decide contractual questions if within "medical necessity," and the regulations specify when a reviewer must use a "contract specialist" instead of a medical reviewer. WAC 246-305-040(4), (5), WAC 246-305-010(9).

Our review raised concerns as to whether IROs are following these guidelines. This should be carefully monitored. The OIC database should track the assignment of qualified decisionmakers to decide contractual issues by requiring that IROs (a) identify any appeal that involves a contractual issue, and (b) identify the qualifications of the reviewer of such an issue. These recommendations are reflected in our suggestions for database elements. If OIC finds medical expertise necessary in managing the IRO system, persons with such expertise could be retained on a consultative basis when auditing IROs or contemplating enforcement.

#### **VIII. Conclusion**

Revisions to the laws and regulations governing IRO decisions can greatly improve the functionality, accountability and quality of the health insurance appeals system. We look forward to the results of reform efforts underway in OIC, DOH, and the Legislature.

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#### **APPENDIX A: Low reversal rates in Washington**

While the summary reports we received are insufficient to provide a complete statistical analysis, the 2012 annual summary reports from seven IROs reflect an average reversal/overturn rate of approximately **25 percent** (71 overturned out of 279). The two annual reports from 2011 showed an average reversal rate of **24 percent** (3/22 = 14 %; 16/45 = 29 %).

Moreover, presumably based on complete statistics for **2008-2010**, OIC reported that **"22 percent** of consumers with fully-insured health plans who requested an external appeal by an *independent review organization* were successful. (Source: WA Department of Health, 2011)."

The **2006** summary of a few IRO decisions from one IRO showed an average reversal rate of only **9 percent**.

These figures reflect a low rate for Washington, compared to the reversal rates across the country. For example, in 2006, the federal Government Accountability Office found that 25 percent was the **floor** for reversals: between one-quarter and one-half of appeals in six states were overturned. See also rates listed at "A Consumer's Guide To Handling Disputes With Your Employer Or Private Plan: 2005 Update," Consumer's Union (Aug. 2005), at <a href="http://nairo.org/site/1920nair/7350consumerguidev4">http://nairo.org/site/1920nair/7350consumerguidev4</a> 080805.pdf. Si

In California, the data show that in **2010**, independent reviewers overturned the insurer's denial in **46 percent** of all IMR cases, requiring the health plan to provide coverage for the care sought by the enrollee. The overall reversal rate in California has increased slightly over time. Ten Years Report, at pp. 9-10 (in 2001-02, IMRs upheld 58% of carrier decisions, making the overturn rate 42% for 1,400 reviews); at pp. 15-16 (noting increase in overturn results for bariatric surgery as the treatment's acceptability rose; while IMRs for bariatric surgery decreased).

The 2012 California Department of Managed Health Care (DMHC) Summary Report further breaks down the statistics for that year: "Overall, enrollees received the requested services in more than 60% of the cases qualified by the Department for the IMR program. In nearly one

ix http://www.insurance.wa.gov/your-insurance/health-insurance/appeal/documents/appeals-guide.pdf, page 5.

<sup>&</sup>lt;sup>x</sup> GAO, *Private Health Insurance: Data on Application and Coverage Denials* (Washington, D.C. 2011).

<sup>&</sup>quot;In North Carolina, consumers were granted relief through external review 45% of the time (43% of the health plan denials were overturned and in 2% of the cases, health plans reversed their denials decisions) during 2003 and 2004. In 2003, Maine consumers were successful 57% of the time (43% full reversals and 14% partial reversals of the health plan denials). The success rate for Texans who appealed in 2004 was 57% (49% in favor of the consumer and 8% partially in favor of both the consumer and the HMO). The success rate was 42% in Indiana in 2003, 39% in California in 2004, and 42% in New York in 2003 (35% health plan denials were reversed in full and 7% were reversed in part). An earlier study with data from the late 1990s and early 2000s found that, on average, consumers were granted relief through external review almost half (45%) of the time. However, the percent varied by state, from a low of 21% in Arizona and Minnesota to a high of 72% in Connecticut. In addition, in about half of the states, reviewers could partially overturn a health plan denial, which they did, on average, 6% of the time." (Footnotes omitted.)

xii California Health Care Foundation, *Ten Years Report*, at 13 (Jan. 2012):

<a href="http://www.chcf.org/~/media/MEDIA%20LIBRARY%20Files/PDF/I/PDF%20IndependentMedicalReviewHistory.pdf">http://www.chcf.org/~/media/MEDIA%20LIBRARY%20Files/PDF/I/PDF%20IndependentMedicalReviewHistory.pdf</a>;

<a href="http://www.chcf.org/publications/2012/01/independent-medical-review-history">http://www.chcf.org/publications/2012/01/independent-medical-review-history</a>.

quarter of the cases (23%), the health plan reversed its denial after the Department received the IMR application, but prior to review by the Independent Medical Review Organization (IMRO). In more than one third of the cases (38%) the IMRO overturned the health plan's prior denial. In about 40 percent of the cases (39%) the IMRO upheld the health plan's prior denial." *Ten Years Report*, at 9.

And yet the 2010 Report stated that California's IMR rate "remains relatively low compared to the number of insured Californians who could access IMR .... Previous research has suggested that California's IMR rate is lower than in some other states." *Id.* at 10-11.

As of 2010, California had addressed nearly 12,000 IMRs through CDI or DMHC. Id.xiii

While we do not know the number of IROs conducted in **Washington** since 2000, based on the IRO decisions listed in the 2012 annual summary reports (total of 279), the total **would likely be much less than 4,000** (for example, 279 in 2013 x 14 years = 3,906; however, during the decade 2000-2010, the volume of reviews would probably have been less than 200).

The California *Ten Years Report* explains that comparisons among states are "hard to interpret" because the rates depend on the number of insured consumers in a state (not always accurately or consistently reported); the rate may be influenced by the prevalent type of coverage offered in a state (traditional indemnity insurance/PPO coverage may have a lower rate of service denials than in states with higher HMO enrollment); and consumers might have other remedies available in other states. *Ten Years Report*, at 11.

### APPENDIX B: Comparison of Washington's and California's requirements for independent review decisions

## Washington's current requirements for IRO decisions:

## WAC 246-305-060, "Criteria and considerations for independent review determinations":

- "Medical necessity and appropriateness Criteria and considerations. Only clinical
  reviewers may determine whether a service,
  which is the subject of an adverse decision, is
  medically necessary and appropriate. These
  determinations must be based upon their
  expert clinical judgment, after consideration
  of relevant medical, scientific, and costeffectiveness evidence, and medical
  standards of practice in Washington state."
- -Medical standards of practice include the standards appropriately applied to physicians or other health care providers, as pertinent to the case.
- -In considering medical standards of practice in Washington, clinical reviewers may use national standards of care, unless presented with evidence that the standard is different in Washington. A service or treatment should be considered Washington standard of practice if reviewers believe that failure to provide it would be inconsistent with that degree of care, skill and learning expected of a reasonably prudent health care provider acting in the same or similar circumstances. Medical necessity will be a factor in most cases.
- -When a review requires making determinations about the application of health plan coverage provisions to issues concerning health care services, these decisions must be made by a "contract specialist", WAC 246-305-040(4); but medical necessity by itself does not require a

#### California's requirements for IMR decisions:

## Cal Health & Safety Code § 1374.33((b); Cal. Ins. Code § 10169.3(b)

Following IMR review, the reviewer(s) shall determine whether the disputed health care service was **medically necessary** based on the specific medical needs of the enrollee and any of the following:

- (1) Peer-reviewed scientific and medical evidence regarding the effectiveness of the disputed service.
  - (2) Nationally recognized professional standards.
  - (3) Expert opinion.
- (4) Generally accepted standards of medical practice.
- (5) Treatments that are likely to provide a benefit to a patient for conditions for which other treatments are not clinically efficacious.
- (c) The organization shall complete its review and make its determination in writing, and in layperson's terms to the maximum extent practicable ....

# Experimental/investigational determinations are governed by Cal. Health & Safety Code § 1370.4 (and Cal. Ins. Code § 10145.3):

- -Plans must provide IMR for "experimental or investigational therapies" for enrollees who meet all of the following criteria:
- life-threatening or seriously debilitating condition (defined by statute);
- enrollee's physician certifies that the enrollee has a condition (defined in statute) for which standard therapies have not been effective in improving the condition, for which standard therapies would not be medically appropriate for the enrollee, or for which there is no more

contract specialist.

- beneficial standard therapy covered by the plan than the therapy proposed;
- Either (A) the enrollee's physician recommended a drug, device, procedure, or other therapy that the physician certifies in writing is likely to be more beneficial to the enrollee than any available standard therapies, or the enrollee, or (B) the enrollee's physician who is a licensed, board-certified or boardeligible physician in the practice requested a therapy that, based on two documents from the medical and scientific evidence (defined in statute), is likely to be more beneficial for the enrollee than any available standard therapy. The physician certification must include a statement of the evidence relied upon by the physician.
- The enrollee has been denied coverage by the plan for a drug, device, procedure, or other therapy recommended or requested.
- The specific drug, device, procedure, or other therapy would be a covered service, except for the plan's determination that the therapy is experimental or investigational.
- The plan's decision to delay, deny, or modify experimental or investigational therapies shall be subject to the IMR process in 1374.33 et seq., except that, instead of information requested in .33(b), the reviewer shall base his or her determination on relevant medical and scientific evidence, including, but not limited to, the medical and scientific evidence defined in 1370.4(d).
- Each expert's analysis and recommendation shall be in written form and state the reasons the requested therapy is or is not likely to be more beneficial for the enrollee than any available standard therapy, and the reasons that the expert recommends that

the therapy should or should not be provided by the plan, citing the enrollee's specific medical condition, the relevant documents provided, and the relevant medical and scientific evidence, including, but not limited to, the medical and scientific evidence as defined in 1370.4(d), to support the expert's recommendation.

# WAC 246-305-050(5) currently requires the following information to be in the IRO decision for <u>non-</u>

#### experimental/investigational claims:

- (5): "the result and rationale for the determination, including its clinical basis unless the decision is wholly based on application of coverage provisions";
- (5)(a): "Documentation of the basis for the determination shall include references to supporting evidence, and if applicable, the rationale for any interpretation regarding the application of health plan coverage provisions."
- (5)(b): "If the determination overrides the health plan's medical necessity or appropriateness standards, the rationale shall document why the health plan's standards are unreasonable or inconsistent with sound, evidence-based medical practice."
- (5)(c): the qualifications of reviewers but not their identity.

## Beginning on July 1, 2015, all decisions must cite the following:

- The enrollee's medical condition,
- Relevant **documents** in the record, and
- Relevant findings as to whether the service was medically necessary based on the specific medical needs and any of the following:
  - Peer-reviewed scientific and medical evidence regarding the effectiveness of the disputed service;
  - Nationally recognized professional standards;
  - Expert opinion;
  - Generally accepted standards of medical practice;
  - Treatments that are likely to benefit a patient for a condition as to which other treatments are not clinically efficacious.

Cal. Health & Safety Code § 1374.33(d), (b); Cal. Ins. Code § 10169.3(d), (b) (eff. July 1, 2015).

Experimental/investigational are subject to substituted requirements in Cal. Health & Safety Code § 1370.4/ Cal. Ins. Code § 10145.3 for "findings" above:

"Medical and scientific evidence" means the following sources:

- Peer-reviewed scientific studies published in or accepted for publication by medical journals that meet nationally recognized requirements for scientific manuscripts and that submit most of their published articles for review by experts who are not part of the editorial staff.
- Peer-reviewed literature, biomedical compendia, and other medical literature that meet the criteria of the National Institutes of Health's National Library of Medicine for indexing in Index Medicus, Excerpta Medicus (EMBASE), Medline, and MEDLARS database of Health Services Technology Assessment Research (HSTAR).
- Medical journals recognized by the Secretary of Health and Human Services, under Section 1861(t)(2) of the Social Security Act.
- Either of the following reference compendia:
  - The American Hospital Formulary Service's Drug Information.
  - The American Dental Association Accepted Dental Therapeutics.
- Any of the following reference compendia, if recognized by the federal Centers for Medicare and Medicaid Services as part of an anticancer chemotherapeutic regimen:
  - The Elsevier Gold Standard's Clinical Pharmacology.
  - The National Comprehensive Cancer Network Drug and Biologics Compendium.
  - The Thomson Micromedex DrugDex.
- Findings, studies, or research conducted by or under the auspices of federal government agencies and nationally recognized federal research institutes, including the Federal Agency for Health Care Policy and Research, National Institutes of Health, National Cancer

Institute, National Academy of Sciences, Health Care Financing Administration, Congressional Office of Technology Assessment, and any national board recognized by the National Institutes of Health for the purpose of evaluating the medical value of health services.

 Peer-reviewed abstracts accepted for presentation at major medical association meetings.

## WAC 246-305-051 requires additional information for <u>experimental or</u> investigational treatment reviews:

- A description of the enrollee's medical condition;
- -A description of the indicators relevant to determining whether there is sufficient evidence to demonstrate that the service or treatment is likely to be more beneficial to the enrollee than any available standard services or treatments and the adverse risks would not be substantially increased over those of available standard health care services or treatments;
- -A description and analysis of any medical, scientific evidence, or cost-effectiveness evidence as defined in WAC 246-305-010(21)("published evidence on results of clinical practice of any health profession which complies with one or more of the following requirements", including peer-reviewed scientific studies, literature, medical journals, research, clinical practice guidelines, and abstracts for presentation at major scientific or clinical meetings).
- A description and analysis of any evidence-based standard as defined in WAC 246-305-010(12);
   and
- -Information on whether the reviewer's rationale for the opinion is based on subsection (2)([d])(i) or (ii) ("(i) The terms of coverage under the enrollee's health benefit plan would have covered the treatment had

the carrier not determined that the	
treatment was experimental or	
investigational; (ii) The recommended or	
requested health care service or treatment	
has been approved by the federal Food and	
Drug Administration, if applicable, for the	
condition"). WAC 246-305-051(3).	
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#### **ENDNOTES**

<sup>1</sup> In the current system, DOH certifies IROs and regulates much of the IRO program, with OIC managing a rotational registry of IROs. IRO decisions are collected by DOH, without any organization. Consequently, IRO decisions cannot be easily found and read, and systemic problems cannot be identified and resolved. Given the lack of availability, it is not possible to determine whether any IRO decisions have previously overturned similar claim denials, for example, when an insurer refused to provide treatment for colon cancer or autism therapy.

DOH has no special expertise to add to the IRO process, and in fact, its involvement with the split in regulatory authority complicates matters while diluting accountability for proper administration of the IRO process. DOH possesses little information about providers through their licenses. DOH does not proactively oversee the provision of care but rather reacts to specific complaints about providers. DOH is not involved in insurers' decisions about benefits.

An analysis of the first 10 years of California's independent review system (2001-2010) observed that it is California's "rich repository of data and information, developed since the CA-IMR program's inception, which formed the basis of the analysis presented" in that report. The data collected put California "in a strong position to review and analyze the program". This analysis led the State Legislature to amend the relevant statutes in 2012 (discussed in Section V.A.). California Health Care Foundation, *Ten Years of California's Independent Medical Review Process*, at 25 (Jan. 2012) (*Ten Years Report*); <a href="http://www.chcf.org/~/media/MEDIA%20LIBRARY%20Files/PDF/I/PDF%20IndependentMedicalReviewHistory.">http://www.chcf.org/~/media/MEDIA%20LIBRARY%20Files/PDF/I/PDF%20IndependentMedicalReviewHistory.</a> California's IMR process has undergone "several published studies reviewing the program's impact and effectiveness." *Id.* at 9 (citing 2001 & 2004 studies). *See* Section V.A.

Following are tables showing Phases 1 and 2, from <a href="http://www.insurance.wa.gov/find-companies-and-agents/iro-transparency/">http://www.insurance.wa.gov/find-companies-and-agents/iro-transparency/</a>:

Phase 1 2014 IRO transparency report (2013 data) (Excel, 27KB) (updated 12/11/2014).

http://www.insurance.wa.gov/find-companies-and-agents/iro-transparency/. Phase 1 of this project, released in December 2014, is a 2013 description of the project and excel spreadsheet showing which health insurers requested an IRO and other limited data about the process. Phase 2, expected in April 2015, will make IROs' annual reports public, along with limited information on the outcomes of all appeals. In Phase 3, later in 2015 or 2016, OIC will release a searchable database of all IRO decisions, which will include detailed case information.

INSURER REQUESTING IRO	DATE INSURER RECEIVED REQUEST FOR IRO	IRO ASSIGNED .	DATE INSURER ASSIGNED IRO	WAS I	NMENT	DID IN SURER FOLLOW SEQUENTIAL ORDER IN A SSIGNING IRO?	
Aetna	1/14/2013	Virginia Health Quality     Center     Medical Review Institute	1/15/2013	Yes		Yes	
Aetna	1/29/2013	of America, Inc. 6. Center for Health Dispute	2/1/2013	yes		yes	
Aetna	2/5/2013	Resolution/MAXIMUS, Inc. /, All med Healthcare	2/8/2013	yes		yes	4
Aetna	2/12/2013	Management 8. National Medical	2/12/2013	yes		yes	
Aetna	3/19/2013	Reviews, Inc.	3/20/2013	yes		yes	

#### Phase 2 (estimated April 2015) is:

IRO Annual Report									
Patient Name	Office of the Insurance Commissioner (OIC) Confirmation Number	Insurer/Carrier Name and WA OIC Number	Treatment or Procedure Under Review	Type of Case  Contract  Medical Necessity  Experimental Investigational	Standard or Expedited Review	Case Determination Upheld Overtuned	# and Nature of Complaints	Compliance with Timeline Y/N	Compliance with Conflict of Interest Rules Y/N

### <sup>4</sup> WAC 246-305-040(4) and (5) provide:

- (4) Contract specialists must be knowledgeable in health insurance contract law, as evidenced by training and experience, but do not need to be an attorney or have any state credential.
  - (5) Assignment of appropriate reviewers to a case.
- (a) An IRO shall assign one or more expert reviewer to each case, as necessary to meet requirements of this subsection.
- (b) Any reviewer assigned to a case shall comply with the conflict of interest provisions in WAC 246-305-030.
- (c) The IRO shall assign one or more clinical reviewers to each case. All clinical reviewers assigned to a case shall each meet the following requirements: ...
- (d) If contract interpretation issues must be addressed, a contract specialist must be assigned to the review.

<sup>&</sup>lt;sup>5</sup> WAC 246-305-010(9) provides: " 'Contract specialist' means a reviewer who deals with interpretation of health plan coverage provisions. If a clinical reviewer is also interpreting health plan coverage provisions, that reviewer shall have the qualifications required of a contract specialist."

<sup>&</sup>lt;sup>6</sup> Laws of 2000, ch. 5 §§ 11-12 (SSB 6199), codified as RCW 48.43.500 (statement of intent), RCW 48.43.535 (authorizing OIC to create rotational registry of certified independent review organizations

(IROs)); WAC 284-43-630 (OIC regulations); RCW 43.70.235 (DOH certification of IROs); WAC Chapter 246-305 (DOH regulations).

#### <sup>7</sup>DOH website:

http://www.doh.wa.gov/AboutUs/ProgramsandServices/HealthSystemsQualityAssurance/IndependentReviewOrganizationsIROs. The DOH website directs consumers to OIC for information about appeal rights.

OIC website: <a href="http://www.insurance.wa.gov/for-insurers/filing-instructions/file-iro-independent-review-organization/">http://www.insurance.wa.gov/for-insurers/filing-instructions/file-iro-independent-review-organization/</a> (assignment instructions to carriers when they receive an independent review request; list of certified IROs). When "independent review" is searched on the OIC website, instructions for IRO assignments appear.

The OIC handbook for consumers on "How To Appeal: A Guide for Consumers in Washington State" (August 2011) is at <a href="http://www.insurance.wa.gov/your-insurance/health-insurance/appeal/documents/appeals-guide.pdf">http://www.insurance.wa.gov/your-insurance/appeal/how-to-appeal/.</a>

DOH has audit and investigation powers over IROs, though these powers are permissive and not mandatory: WAC 246-305-100 provides:

- (1) The department may deny, suspend, revoke, or modify certification of an IRO if the department has reason to believe the applicant, certified IRO, its agents, officers, directors, or any person with any interest in the IRO has failed or refused to comply with the requirements established under this chapter.
- (2) The department may conduct an on-site review, audit, and examine records to investigate complaints alleging that an applicant, certified IRO, or reviewer committed any conduct described in WAC 246-305-110.

OIC has no counterpart to this DOH regulation.

In California, DMHC is <u>required</u> to perform an annual audit. Cal. Health & Safety Code § 1374.34(e).

The decisions in Segments 2-8 of the production (1,500 pages), all from 2013, are by the following IROs:

- AllMed
- IMedecs (Independent Medical Consulting Network Services, Inc.)

<sup>&</sup>lt;sup>8</sup> The provisions of this chapter include requirements for certification, conflict of interest, expert reviewers, "Independent review process," additional requirements for experimental or investigational treatment reviews, application for certification, grounds for action against an applicant or certified IRO, maximum fee schedule, and powers of DOH.

<sup>&</sup>lt;sup>9</sup> In response to a public records act request made in May 2014, DOH produced over 2,000 pages of records by September 2014. Almost all of the production consisted of IRO decisions made in 2013 by eight IRO companies. Also included in the production were seven IROs' annual summary reports for 2012 (for a total of **279 IRO decisions in 2012**), two annual summaries from 2011, and one from 2006, as well as emails concerning specific IRO decisions or issues in OIC's management of the process.

- IMX Medical Management Services
- IPRO
- MAXIMUS Federal Services, Inc. (the sole IRO contracting with CDI and DMHC in California)
- MCMC
- MCN (Medical Consultants Network)
- National Medical Reviews, Inc. (one page forms with little information)
- VQHC

The decisions in the production numbered 5361 are from 2014 through 2011:

- Pp. 1-25 are the seven 2012 annual report summaries;
- Pp. 26-451 relate to an independent review of a cytoreductive surgery claim, which was overturned by MCMC (other decisions overturning Premera's previous denials of the same procedure are included in these pages);
- Pp. 452-59 relate to an appeal of leg surgery;
- Pp. 460-503 concern ABA treatment for autism;
- Pp. 504-15 address insurers' misreading of the regulation listing possible bases for review as exclusive rather than a sampling;
- Pp. 516-23 relate to a partial overturn;

Pp. 536-558 (apart from some annual summaries) include miscellaneous IRO decisions, possibly by Medical Review Institute of America, Inc. (no identification of IRO).

<sup>10</sup>There are 14 IROs currently listed as certified on the OIC website. <a href="http://insurance.wa.gov/for-insurers/filing-instructions/file-iro-independent-review-organization/iro-instructions/">http://insurance.wa.gov/for-insurers/filing-instructions/file-iro-independent-review-organization/iro-instructions/</a>. When carriers receive a request for independent review, they are required to assign an IRO from the rotational registry, selecting the listed IROs for referral of a request in the order presented.

By contrast, in California, one IRO has contracted with DMHC and CDI to do all IMRs – MAXIMUS Federal Services, Inc. *Ten Years Report*, at 4.

<sup>&</sup>lt;sup>11</sup> See also WAC 284-43-615, -620 (general grievance and complaint procedures; procedures for review and appeal). <a href="http://insurance.wa.gov/for-insurers/filing-instructions/file-iro-independent-review-organization/">http://insurance.wa.gov/for-insurers/filing-instructions/file-iro-independent-review-organization/</a>iro-instructions/ (updated 6/6/14); <a href="http://insurance.wa.gov/for-insurers/filing-instructions/file-iro-independent-review-organization/assignments-form/">http://insurance.wa.gov/for-insurers/filing-instructions/file-iro-independent-review-organization/assignments-form/</a> (updated 12/12/14).

<sup>&</sup>lt;sup>12</sup> In 2010-11, the Departments of Labor, Health & Human Services, and Treasury issued regulations requiring states to implement an external review process meeting standard set by the National Association of Insurance Commissioners' Uniform Health Carrier External Review Model Act (April 2010), <a href="http://www.naic.org/documents/committees">http://www.naic.org/documents/committees</a> b uniform health carrier ext rev model act.pdf; <a href="http://www.cms.gov/CCIIO/Resources/Files/external\_appeals.html">http://www.cms.gov/CCIIO/Resources/Files/external\_appeals.html</a>. Washington's system meets those standards.

<sup>&</sup>lt;sup>13</sup> OIC decisions on "Hearings cases" are listed at <a href="http://www.insurance.wa.gov/laws-rules/administrative-hearings/judicial-proceedings/a-b/">http://www.insurance.wa.gov/laws-rules/administrative-hearings/judicial-proceedings/a-b/</a>.

14 RCW 48.02.080, "Enforcement," provides:

(1) The commissioner may prosecute an action in any court of competent jurisdiction to enforce any order made by him or her pursuant to any provision of this code.

...

- (3) If the commissioner has cause to believe that any person is violating or is about to violate any provision of this code or any regulation or order of the commissioner, he or she may:
- (a) issue a cease and desist order; and/or
- (b) bring an action in any court of competent jurisdiction to enjoin the person from continuing the violation or doing any action in furtherance thereof.
- (4) The attorney general and the several prosecuting attorneys throughout the state shall prosecute or defend all proceedings brought pursuant to the provisions of this code when requested by the commissioner.

<sup>15</sup> See <a href="www.nairo.org">www.nairo.org</a>. NAIRO is the national accreditation organization, (National Association of Independent Review Organizations), formed by the majority of URAC-accredited IROs. URAC's "standards" are listed at <a href="https://www.urac.org/wp-content/uploads/STDGlance">https://www.urac.org/wp-content/uploads/STDGlance</a> IRO <a href="External.pdf">External.pdf</a> (but as of September 2014, only available to URAC's accreditation customers).

In 2012, URAC and NAIRO issued a White Paper, "Mastering External Appeals". <a href="https://www.urac.org/">https://www.urac.org/</a>.

NAIRO also has some issue briefs at <a href="http://nairo.org/about\_nairo/articles">http://nairo.org/about\_nairo/articles</a>.

<sup>17</sup> We have searched for and inquired about independent review databases in other states and found none.

Apart from California, at least one state (Oregon) makes independent review decisions publicly available:

An independent review organization shall file synopses of its decisions with the director according to the format and other requirements established by the director. The synopses shall exclude information that is confidential, that is otherwise exempt from disclosure under ORS 192.501 ... or that may otherwise allow identification of an enrollee. The director shall make the synopses public.

ORS § 743.862(5) (emphasis added).

Oregon IRO decisions are admissible in a legal proceeding involving the insurer or the enrollee and the disputed issues subject to external review. ORS § 743.863(2). Enrollees who are the subject of an IRO in Oregon have a private right of action against the insurer for damages arising from an adverse determination by the insurer if the insurer fails to comply with the external review. ORS § 743.864(1). The director of may assess a civil penalty against the insurer

<sup>&</sup>lt;sup>16</sup> Specifically, all those in the records from National Medical Reviews, Inc., Segment 7, pages 59-91. Several IRO decisions fail to redact patient names. One technical issue acknowledged by DOH in the first 500 pages of the production is that a few of the records are so poorly scanned that they are incomprehensible; these are in the group regarding the cytoreductive surgery overturned by MCMC.

for failing to comply with an IRO decision. ORS § 743.863. *See also* Oregon Administrative Rules 836-053-1300 - 1365.

https://www.dmhc.ca.gov/FileaComplaint/IndependentMedicalReview%28IMR%29.aspx#.VMP\_qS7fDzN\_. *See also* 

 $\frac{https://www.dmhc.ca.gov/FileaComplaint/IndependentMedicalReviewComplaintForm.aspx\#.VMP\_VC7fDzM;}{https://www.dmhc.ca.gov/FileaComplaint/IndependentMedicalReviewandComplaintReports.aspx\#.VMP\_7\gamma7fDzM]}{https://www.dmhc.ca.gov/FileaComplaint/IndependentMedicalReviewandComplaintReports.aspx\#.VMP\_7\gamma7fDzM]}{https://www.dmhc.ca.gov/FileaComplaint/IndependentMedicalReviewandComplaintReports.aspx\#.VMP\_7\gamma7fDzM]}{https://www.dmhc.ca.gov/FileaComplaint/IndependentMedicalReviewandComplaintReports.aspx#.VMP\_7\gamma7fDzM]}{https://www.dmhc.ca.gov/FileaComplaint/IndependentMedicalReviewandComplaintReports.aspx#.VMP\_7\gamma7fDzM]}{https://www.dmhc.ca.gov/FileaComplaint/IndependentMedicalReviewandComplaintReports.aspx#.VMP\_7\gamma7fDzM]}{https://www.dmhc.ca.gov/FileaComplaint/IndependentMedicalReviewandComplaintReports.aspx#.VMP\_7\gamma7fDzM]}{https://www.dmhc.ca.gov/FileaComplaint/IndependentMedicalReviewandComplaintReports.aspx#.VMP\_7v7fDzM]}{https://www.dmhc.ca.gov/FileaComplaint/IndependentMedicalReviewandComplaintReports.aspx#.VMP\_7v7fDzM]}{https://www.dmhc.ca.gov/FileaComplaint/IndependentMedicalReviewandComplaintReports.aspx#.VMP\_7v7fDzM]}{https://www.dmhc.ca.gov/FileaComplaintPedicalReviewandComplaintReports.aspx#.VMP\_7v7fDzM]}{https://www.dmhc.ca.gov/FileaComplaintReports.aspx#.VMP\_7v7fDzM]}{https://www.dmhc.ca.gov/FileaComplaintReports.aspx#.VMP\_7v7fDzM]}{https://www.dmhc.ca.gov/FileaComplaintReports.aspx#.VMP\_7v7fDzM]}{https://www.dmhc.ca.gov/FileaComplaintReports.aspx#.VMP\_7v7fDzM]}{https://www.dmhc.ca.gov/FileaComplaintReports.aspx#.VMP\_7v7fDzM]}{https://www.dmhc.ca.gov/FileaComplaintReports.aspx#.VMP\_7v7fDzM]}{https://www.dmhc.ca.gov/FileaComplaintReports.aspx#.VMP\_7v7fDzM]}{https://www.dmhc.ca.gov/FileaComplaintReports.aspx#.VMP\_7v7fDzM]}{https://www.dmhc.ca.gov/FileaComplaintReports.aspx#.VMP\_7v7fDzM]}{https://www.dmhc.ca.gov/FileaComplaintReports.aspx#.VMP\_7v7fDzM]}{https://www.dmhc.ca.gov/FileaComplaintReports.aspx#.VMP\_7v7fDzM]}{https://www.dmhc.ca.gov/FileaComplaintReports.aspx#.VMP\_7v7fDzM]}{https://www.dmhc.ca.gov/FileaCom$ 

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https://interactive.web.insurance.ca.gov/IMR/faces/search? afrLoop=711520431413011& afr WindowMode=0& adf.ctrl-state=3zszcrayz 4. See also http://www.insurance.ca.gov/01-consumers/101-help/Independent-Medical-Review-Program.cfm.

- Nearly 12,000 Californians obtained an IMR between 2001 and 2010, with the annual number of IMR cases tripling during this time.
- More than half of IMR cases involved orthopedics, neurology, mental health, or cancer.
- In 46% of IMR cases in 2010, the independent reviewers overturned the original decision and required the health plan to provide coverage.
- IMR cases clustered around situations where the medical knowledge was evolving. Medical consensus correlated with fewer IMRs; lack of medical consensus meant more IMRs.
- Independent reviewers have not always met California IMR standards. Decisions have not been uniformly documented, and reviewers have not always been appropriately credentialed.

http://www.chcf.org/publications/2012/01/independent-medical-review-history#ixzz3Fgab6BLJ.

<sup>22</sup>Cal. Government Code § 11425.60: "(b) An agency may designate as a precedent decision a decision or part of a decision that contains a significant legal or policy determination of general application that is likely to recur." The Cal. Dept. of Insurance has its index of precedential decisions at <a href="http://www.insurance.ca.gov/0250-insurers/0500-legal-info/0600-decision-ruling/">http://www.insurance.ca.gov/0250-insurers/0500-legal-info/0600-decision-ruling/</a>. The vast majority are worker's comp cases. CDI provides this description:

The Insurance Commissioner decides numerous disputes pursuant to authority granted under the Insurance Code. Some of the final decisions arising from these adjudications have been designated as "precedential," pursuant to Government Code section 11425.60. That is, the policies and holdings in these decisions can be relied upon by parties to current cases, cited in their briefs and also relied upon by the Administrative Law Judge in making a proposed decision.

<sup>&</sup>lt;sup>18</sup> New York, among other states, has a similar system of screening requests for independent review. http://www.dfs.ny.gov/insurance/extapp/extappqa.htm.

<sup>&</sup>lt;sup>19</sup>The DMHC website for IMRs is at:

http://www.chcf.org/~/media/MEDIA%20LIBRARY%20Files/PDF/I/PDF%20IndependentMedical ReviewHistory.pdf; http://www.chcf.org/publications/2012/01/independent-medical-review-history. CHCF's website sets forth the Report's key findings as including the following:

#### Recent Decisions and Rulings of Note

Members of the public have expressed interest in having access to certain Commissioner decisions that are not precedential and certain Administrative Law Judge rulings that are not precedential. While these decisions and rulings do not necessarily indicate that another administrative law judge will follow or has even seen the reasoning set forth in those decisions and rulings published here, a request from a member of the public to see a recent decision or ruling will be acco[m]modated by posting it here for a limited time.

This Notice reminds insurers that the California Department of Insurance (CDI) is committed to enforcing the provisions of the Insurance Code governing Independent Medical Review (IMR) of disputed health care services to ensure the full protection under the law of insureds with policies of health care insurance regulated by the CDI. The CDI requires that insurers fully comply with Insurance Code Section 10169 governing IMR as well as with Insurance Code Section 10169.3(f), which specifies that

http://leginfo.legislature.ca.gov/faces/billNavClient.xhtml;jsessionid=6a6ae27f61be2aa7ffa6f4b8097d.

The CHCF report concluded that "several primarily administrative improvements might be made in [California's] IMR, which would position the state to more effectively deliver on the promise of a credible, transparent, and effective IMR program." Senate Health Committee Report (March 29, 2012).

<sup>&</sup>lt;sup>24</sup> Cal. Health & Safety Code §§ 1374.30-33, Cal. Insurance Code §§ 10169-10169.3.

http://www.leginfo.ca.gov/pub/11-12/bill/sen/sb 1401-1450/sb 1410 cfa 20120409 162152 sen comm.html; or http://leginfo.legislature.ca.gov/faces/billTextClient.xhtml (click on 04/09/12 - Senate Health to download Senate Committee on Health bill report).

The current law provides: "After removing the names of the parties, including but not limited to the insurance, all medical providers, the insurer and any of the insurer's employees or contractors, commissioner decisions adopting a determination of an independent medical review organization shall be made available by the department to the public **upon request**, at the department's cost and after considering applicable laws governing disclosure of public records, confidentiality and personal privacy." Cal. H&S Code § 1374.33(g); Cal. Ins. Code § 10169.3(g) (emphasis added). However, as stated above, DMHC has had a searchable database of summaries of the findings in IMR decisions on its website since 2001. Beginning July 1, 2015, decisions will be "made available by the department to the public in a searchable database". Cal. H&S Code § 1374.33(g); Cal. Ins. Code § 10169.3(g).

<sup>&</sup>lt;sup>27</sup> See also discussion of treatment for advanced breast cancer, at page 4, "The Early Case for IMR ...."

http://www.insurance.ca.gov/01-consumers/110-health/upload/NoticeReEnforcementofIMRs.pdf (May 17, 2011: "Enforcement of Independent Medical Review Statutes"). This Notice is interesting for our state because, although it is not a "precedential decision" or the result of a hearing before the agency, it describes and enforces the law governing health carriers:

the Insurance Commissioner's written decisions adopting the determination of the independent medical review organization shall be binding on the insurer. CDI evaluates insurers' communications with insureds regarding coverage of health care services, and payment of claims for those services, for compliance with Insurance Code Section 790.03. This statute defines, and prohibits as unfair methods of competition and unfair and deceptive acts or practices, the following conduct, among other acts: "(a) Making...or causing to be made...any...statement misrepresenting the terms of any policy issued, or the benefits or advantages promised thereby.... \*\*\* (h) Knowingly committing or performing with such frequency as to indicate a general business practice any of the following unfair claims settlement practices: (I) Misrepresenting to claimants pertinent facts or insurance policy provisions relating to any coverages at issue; \*\*\* (5) Not attempting in good faith to effectuate prompt, fair, and equitable settlements of claims in which liability has become reasonably clear ...

The memo goes on to note the CDI identified "nine separate instances in 2010 in which insurers' denials of behavioral therapy such as Applied Behavioral Analysis have been overturned in IMR. In two of those instances, the insurers' denials - based on a contention that the therapy was experimental or investigational - were overturned because such treatment is now recognized as the standard of care for autism. In another seven instances, the IMR reviewers overturned the insurer's denial, finding that the treatment was medically necessary for the insured." *See also* http://www.insurance.ca.gov/01-consumers/110-health/60-resources/05-autism/.

http://www.oregon.gov/DCBS/insurance/news/Pages/2014/nov142014.aspx; http://www.oregon.gov/DCBS/insurance/legal/bulletins/Pages/proposed-bulletin-review.aspx.