



IMPLEMENTING HEALTH CARE REFORM: EXTERNAL REVIEW OF HEALTH PLAN DECISIONS

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New Yorkers for Accessible Health Coverage (NYFAHC) is a statewide coalition of over 50 organizations representing people with disabilities and serious illnesses. NYFAHC leads the way to affordable, accessible, and meaningful health insurance. NYFAHC is an independent program of the Center for Independence of the Disabled, New York (CIDNY). For more information contact Heidi Siegfried, hsiegfried@cidny.org. www.cidny.org.

IMPLEMENTING HEALTH CARE REFORM: EXTERNAL REVIEW OF HEALTH PLAN DECISIONS

EXECUTIVE SUMMARY

If New York wishes to continue to use its highly successful and well-run program providing external review of certain health plan decisions, it must, no later than July 1, 2011, change the laws governing how that program operates to conform to new federal standards mandated under the Patient Protection and Affordable Care Act of 2010 (ACA). If the Legislature fails to give this matter priority at the end of its current session, consumers' opportunity to have disputes over access to treatments resolved under the carefully crafted standards of New York law, by impartial decision-makers selected by the State, may be lost, and consumers may find themselves having to use an unfamiliar federal system which is yet to be developed.

Some of the changes required by ACA are fairly minor, technical changes about which there is little room for debate. New York must:

- extend its deadline for filing requests for review (from 45 days to 4 months);
- reduce the fees charged for review (from \$50 to \$25, with a maximum annual aggregate fee of \$75 for multiple requests);
- only contract with accredited external review organizations;
- permit immediate external review in urgent care situations;
- require expedited external review in continuing treatment situations and when the consumer's chance of regaining full function would otherwise be jeopardized;
- permit non-board-certified doctors to recommend experimental treatments; and
- permit all consumers, not just terminally ill or severely disabled ones, to seek review of experimental treatment denials.

This report also concludes that the ACA requires expansions in the scope of the questions eligible for external review to encompass all matters regarding level of care, appropriateness of care, and health care setting, which may not have been heretofore contemplated by state policy makers. These include:

- Selection of type of specialist;
- Adequacy of in-network specialist;
- Appropriateness of coding; and
- Whether a claim was processed within the appropriate coverage category.

Expanding the scope of questions eligible for external review could be accomplished by amending New York's statutes to mirror the language of the ACA and National Association of Insurance Commissioners (NAIC) Uniform Model Act as to the scope of issues covered, together with repealing the specific exceptions to external review now in New York statute which preclude review of questions of failing to obtain services from a designated network provider, coding disputes, and the like.

This report proceeds to recommend that New York undertake two expansions of the external review system which are not mandated for this year by the ACA but which should significantly strengthen the system by making administration of the system easier for regulators and navigation easier for consumers and those who assist them:

- Opening the external review system to more users. Expanding the number of health plans able to use the system would bolster its resources through new user fees and would bring uniformity of expectations about remedies to a much broader part of the state's populations. Multiple employer welfare arrangements (MEWAs) could be required to use the State's system. Large self-insured employer and union plans governed by ERISA could be invited to use the system on a voluntary basis.

IMPLEMENTING HEALTH CARE REFORM: EXTERNAL REVIEW OF HEALTH PLAN DECISIONS

- Subjecting grandfathered health plans to the new external review rules. The ACA exempts so-called grandfathered plans from its external review rules, but putting all plans under the same standards would avoid a nightmare of regulators and consumers constantly having to determine whether plans have grandfathered status. It would also avoid the unfairness of similarly situated consumers or small groups being covered by the exact same insurance policies but being subjected to different rules and coverage outcomes based on when a policy was first purchased.

The report suggests that New York should also, as it is modifying the external review system, conform its standards for clinical trial coverage to the federal standards that will take effect in 2014. Further evolution of the external review system should, the report concludes, depend upon the sorts of problems for which consumers most seek help from the state's consumer assistance programs and upon the growth in capacity of certified Independent Review Organizations (IROs) to entertain other types of disputes.

This report will briefly recount the history and major features of New York's current state system, and explain why it must change under the ACA. It then catalogues the technical changes which any legislation must have in order to bring the system into full compliance with the ACA and discuss optional changes to the system which may be appropriate to achieve a workable and consumer friendly system.

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IMPLEMENTING HEALTH CARE REFORM: EXTERNAL REVIEW OF HEALTH PLAN DECISIONS

I. INTRODUCTION

A. Background on New York's external review system

"External review" and "external appeal" are terms used to describe the appointment of experts who are not employed by health insurance plans to determine whether those disputed adverse benefit decisions by the plans were correctly made. External review is widely viewed by patient advocates as an essential consumer protection.ⁱ Insurers view it as an economical and fair way to resolve disputes with their enrollees, thereby maintaining good customer relations.ⁱⁱ Academic analysts appear to agree with these positive assessments.ⁱⁱⁱ

Prior to 1990 only Michigan (1978), Florida (1985) and the Medicare program (1989) had programs of external review. Between the mid 1990s and 2002 the vast majority of other states, including New York, established such programs. There are now only five states (Alabama, Mississippi, Nebraska and North and South Dakota) that do not mandate some form of external review.^{iv}

New York's external review program is one of the largest in the country. The system is operated by New York's Insurance Department, in collaboration with the Department of Health. It has approved three different independent review organizations (IROs) to conduct the appeals. In a typical year, between 40% and 50% of the appeals heard result in partial or complete reversal of health plan decisions and additional access to care for consumers. Until the last two years New York's external review system consistently decided more disputes than any other state. Indeed, in a national study of external review systems using data from 2003 and 2004, AHIP Center for Policy and Research found that New York accounted for roughly 20% of all national external appeals.^v From the system's start up in July, 1999, through December 31, 2009, the last period for which figures are available, New York received 25,839 appeal requests. In 2009, alone, it decided 2,033 external appeals. One measure of the system's success is that its decisions are rarely challenged. Although courts have recognized that consumers who do not prevail at external review may still sue to obtain benefits,^{vi} there are very few reported cases in which consumers have tried to sue despite adverse external review decisions.

When enacted in 1998, New York's program had jurisdiction over health plans' denials of coverage based on determinations that treatments were not medically necessary, or, in cases where the covered person had a life-threatening or seriously disabling disease, that the treatments were experimental or investigational. The latter category includes prescriptions of "off-label" drugs (for purposes other than specified in federal Food and Drug Administration labeling) and for treatments in clinical trials. In that respect, it has had broader scope than the programs of many states, which deal solely with medical necessity determinations, but narrower than some states which include such issues as whether a medical service is excluded from coverage because it is treating a pre-existing condition.

A few states permit review of virtually all disputed claim determinations by insurers.^{vii} New York has over time expanded the law to permit providers, as well as consumers, to pursue concurrent or retrospective adverse claim determinations (2007), to include specific standards for denials of experimental treatments in the case of rare diseases (2009), and to address disputes over access to out of network treatment when the type of treatment offered by the plan in-network is believed to be materially different from the treatment sought by the consumer (2009). The vast majority of external reviews have involved disputes between consumers and their health plans over whether treatments were medically necessary. A much smaller number involved health plan refusals to cover treatments that were claimed to be experimental and investigational.

IMPLEMENTING HEALTH CARE REFORM: EXTERNAL REVIEW OF HEALTH PLAN DECISIONS

Since the middle of the last decade, as reported in the annual reports of the New York Insurance Department, the number of applications for external review has grown steadily each year. Apparently, the public's expectations that the system can resolve all sorts of disputes have grown as well. The proportion of applications for review that are rejected as ineligible to participate in the system has consistently grown, to the point where over 4 in 10 applications for review are now rejected.

B. The effects of federal health reform on New York's external review system

Federal health care reform, enacted by the Patient Protection and Affordable Care Act of 2010^{viii} ("the ACA"), recognizes external review as a fundamental aspect of consumer protection in all health plans. It thus requires all plans other than "grandfathered plans" (plans already in existence on the date the ACA was enacted, March 23, 2010, which under the terms of the law consumers and employers are permitted to keep if they wish as long as the insurer continues to offer it^{ix}) to provide external review. This means much more than simply expanding external review to the five states that do not have a system. It also means that the self-insured health plans, to which state external review requirements could not be extended,^x must begin to offer external review, and that the state systems for insured plans must meet basic federal standards.

The basic federal standards established by the ACA are those of a model law developed by the National Association of Insurance Commissioners ("NAIC"). The NAIC, founded in 1871, is an organization composed of the public officials, both elected and appointed, who regulate the business of insurance in all American states and territories. The NAIC serves as a technical resource and forum for exchange of ideas, assisting these officials in their mission of protecting the public interest, promoting competitive markets, facilitating fair treatment of insurance consumers, promoting the reliability, solvency and financial solidity of insurance institutions; and supporting and improving state regulation of insurance.^{xi} In aid of that effort, the NAIC has long created model legislation which states may enact as written or adapt to their own needs. Among that body of model legislation is the Uniform Health Carrier External Review Model Act (the "NAIC Uniform Model Act").^{xii}

The ACA requires that all State laws give consumers at least the external review rights contained in the NAIC Uniform Model Act as it existed on March 23, 2010. The new federal rules took effect on September 23, 2010, for plan years^{xiii} beginning on or after that date.^{xiv} They do not affect grandfathered plans in effect on or before March 23, 2010.^{xv} In July, 2010, The Departments of Health and Human Services, Treasury and Labor published provisional regulations in the Federal Register, Interim Final Rules for Group Health Plans and Health Insurance Issuers Relating to Internal Claims and Appeals and External Review Processes Under the Patient Protection and Affordable Care Act ("Interim Final Rules") in which they determined that for state external review systems to be deemed to provide the protections of the NAIC Uniform Model Act, they must contain 16 specified consumer protections, which are printed in Appendix One to this report. The new federal standards are clear, however, that they do not preempt state laws that impose stricter requirements on health plans, unless the state laws make it impossible to enforce provisions of the ACA.^{xvi}

Those states like New York which had external review systems as of July 23, 2010, but which did not contain all the essential elements of the model law were given until July 1, 2011, to come into compliance. During that period, plans subject to the law could continue to use the existing state system. For plan years beginning after July 1, 2011, if a state's system has not been conformed to the NAIC Uniform Model Act as it existed on July 23, 2010, insurers and plans would have to start using a new federal external review system^{xvii}.

IMPLEMENTING HEALTH CARE REFORM: EXTERNAL REVIEW OF HEALTH PLAN DECISIONS

II. WHAT PROVISIONS OF STATE LAW MUST BE CHANGED TO MEET FEDERAL STANDARDS?

The most critical priority for New York in maintaining its external review system is making the modifications necessary to meet the new federal standards for such review on or before July 1, 2011. There are several areas where current New York law and the federal standards differ. Some of the new federal rules regarding external review are more protective of consumer rights than our current state rules. Others are less so. As reflected in the inventory below, New York does not need to revise its statute with respect to rules which offer greater protection to consumers than the federal rules, but should revise those provisions that do not meet the federal standards.

A. Certification Standards for Independent Review Organizations

The existing New York statute, codified at Insurance Law §4912 and Public Health Law §4912, has extensive certification requirements for independent review organizations, including that the reviewers who perform the reviews for the IROs be appropriately licensed. It does not require, however, that the IRO itself have any accreditation. Such accreditation by a nationally recognized private accrediting organization is required by the new federal standards. New York's currently approved IROs are all accredited by URAC, a national accreditation body for IROs, so adding this requirement would not affect the availability of review under the current system. Nevertheless, the statute will have to be amended to add such an accreditation requirement for IROs.

B. Record Keeping

The Interim Final Rules require that IROs maintain written records of their operations for a six-year period and to make them available for review. Ins. L. §4912(e) currently requires the IRO to "provide ready access to the superintendent to all data, records, and information collected and maintained concerning such agent's external appeal activities." While there is no specific statutory provision requiring the IRO to keep records of its operations for six years, Insurance Department and Health Department regulations do contain this requirement^{xviii}, and that should suffice to bring New York into compliance with the ACA without statutory change.

C. Filing fees

The new federal standards require that no more than a nominal fee of \$25 (waivable in case of hardship) be charged to a consumer for an external review request, and no more than an aggregate of \$75 be charged for all external review requests by a consumer in a single calendar year. The current New York statute requires a \$50 fee, and does not provide an out-of-pocket maximum for such fees in the event of multiple external reviews. The federal standards will have to be adopted.

D. Time To File

The new federal standards permit consumers up to four months after receipt of a notice of a final internal adverse determination to file a request for external review. Current New York law permits only 45 days. The four-month filing deadline will have to be adopted. Data published by the New York Insurance Department in its 2005 annual report on the external review system suggests that extension of the filing deadline will have a positive effect in reducing the number of filings rejected by the Department, as one of the most common reasons for rejection was late filing.

IMPLEMENTING HEALTH CARE REFORM: EXTERNAL REVIEW OF HEALTH PLAN DECISIONS

E. Exhaustion of Internal Appeals

Current New York law requires that consumers and providers filing appeals always exhaust the first level of internal appeal before filing a request for external review, unless the plan agrees to waive the internal review. The new federal standards permit an applicant in an urgent care situation to file an expedited external review request simultaneously with filing a request for an expedited first internal review. New York will have to adopt a similar rule.

The new federal standards also deem that the consumer has exhausted claim and appeal processes if the health plan does not comply with strict deadlines for decisions or a number of other rules regarding notice and consideration of internal appeals.^{xix} In its March 18, 2011, revision of the Interim Final Rules, the Department of Labor postponed the effective date of this "strict compliance" rule to plan years beginning on and after January 1, 2012. New York law already has considerably more strict penalties than the ACA for plans that do not meet their deadlines. At the first level of utilization review, a health plan's failure to comply strictly with decisional time deadlines is deemed an "adverse determination", permitting the consumer to proceed with an appeal; if the appeal itself is not decided in the time required, the initial denial is deemed reversed.^{xx} While the State rules regarding deadlines for decision are more protective of consumers than the new federal standards, and need not be changed, New York should conform its rules to allow consumers to proceed directly to external review when other appeal processing rules have been violated by their health plans.

F. Binding Nature of Decision

Current New York statute provides that the external review decision is "binding on the plan and the insured" but is "admissible in any court proceeding." Insurance Law. §4914; Public Health Law §4914. Insurers have relied on the "binding nature" language to argue that consumers have no right to sue in order to obtain benefits if those benefits are not awarded at external review. New York courts have relied on the language regarding admissibility in court to find that consumers do retain the right to sue.^{xxi}

The new federal standards provide that external review decisions are binding except "to the extent the other remedies are available under State or Federal law." It is not clear whether these "other" remedies referred to would include the right to sue for benefits under ERISA, for example, or under State contract law for individual policies, or whether the "other remedies" refers only to remedies under other types of statutes, such as consumer fraud statutes. As noted above, New York's statute, because it authorizes admission into evidence of external review decisions, has been interpreted to implicitly authorize consumer suits for benefits under ERISA or state contract law even if they lose their external appeals. Federal law certainly permits New York to be more consumer protective in this regard by keeping the law as it currently exists, so even if the federal rules are interpreted more strictly, no change would appear to be required to the existing statute.

G. Experimental Treatment Review

Under the Interim Final Rules, New York must provide protections regarding experimental treatment "substantially similar to" Section 10 of the NAIC Uniform Model Act on external review. The NAIC Uniform Model Act affords external review to any consumer who has received an adverse claim determination based on an experimental treatment exclusion.

New York law currently provides review of disputes centering on allegedly experimental or investigational treatments only to consumers with life-threatening or seriously disabling conditions. To comply with the new federal standards, New York must provide such review to all

IMPLEMENTING HEALTH CARE REFORM: EXTERNAL REVIEW OF HEALTH PLAN DECISIONS

consumers. The author has been advised that the Insurance Department is waiting for clarification from the federal authorities as to whether such a change is in fact required. It appears, however, that such clarification should be unnecessary. Excluding any consumers from access to review of experimental treatment decisions would be less protective of consumers than the ACA, and therefore the New York statute must be amended.

The Interim Final Rules and the NAIC Uniform Model Act on which it is based also permit an insured person's treating physician to certify the expectation of a better outcome for a treatment which has been denied as experimental or investigational without regard to whether that physician is board certified (except in cases where the opinion is based on scientific literature). New York's Insurance Law requires that in all cases the physician be board certified. The board certification requirement should be removed from New York statute where it is the treating physician who is certifying the advantages of the treatment.

The NAIC Uniform Model Act also requires that a reviewer of an experimental treatment on external review have three years recent clinical experience in treating the condition at issue. New York Insurance Law § 4900 defines a clinical peer reviewer for purposes of external review as a board certified physician who has been practicing at least five years in the relevant specialty. The additional two years of practice required by New York would appear to be more consumer protective and therefore not preempted by the ACA, so that no statutory change by New York is required in this regard.

H. Timelines for External Review

The new federal standards mandate expedited review when the prescribing physician certifies that a decision on the standard schedule would "seriously jeopardize the life or health of the covered person" or "jeopardize the covered person's ability to regain maximum function." They also require expedited review if the issue involves admission to or continued stay at a facility where the covered person received emergency services.^{xxii} New York law currently only authorizes expedited external review when delay in the decision would pose "an imminent or serious threat to the health of the insured." Expedited review on grounds of loss of opportunity to regain maximum function and with respect to admission or continuing stay for certain patients should be added to New York's statute.

Both the Interim Final Rules and existing New York law provide 72 hours for decisions on expedited external review. Even though the NAIC Uniform Model Act requires a 48 hour decisional turnaround, the specific provisions of the ACA would appear to govern on this issue so that New York's time for expedited external review is already in compliance with the ACA.

For non-expedited review, the Interim Final Rules require decision within 45 days. New York requires decisions within 30 days, and therefore already exceeds the ACA's requirements. No statutory change is required.

I. Subjecting additional health plan decisions to external review: setting of care, level of care and access to specialists.

The new federal standards require that external review address several types of health plan decisions: those regarding medical necessity, level of care, appropriateness, effectiveness, and health care setting. The ACA makes many other issues the subject of internal appeal, including rescissions, issues of individual eligibility for coverage, and all other adverse benefit determinations (required changes to the internal review system will be discussed in a

IMPLEMENTING HEALTH CARE REFORM: EXTERNAL REVIEW OF HEALTH PLAN DECISIONS

forthcoming issue brief on that topic). But it does not mandate that those disputes be subject to external review.

New York's statute currently takes a limited view of what decisions reflect judgments of "medical necessity" and may be subject to external review. To ensure its narrow application, the statute makes clear that a number of common consumer/plan disputes, including many disputes which involve the application of medical judgment, are outside the scope of "utilization review" and therefore outside the external review system:

For the purposes of this article none of the following shall be considered utilization review:

- (1) Denials based on failure to obtain health care services from a designated or approved health care provider as required under a contract;
- (2) Where any determination is rendered pursuant to subdivision three-a of section twenty-eight hundred seven-c of the public health law^{xxiii};
- (3) The review of the appropriateness of the application of a particular coding to a patient, including the assignment of diagnosis and procedure;
- (4) Any issues relating to the determination of the amount or extent of payment other than determinations to deny payment based on an adverse determination; and
- (5) Any determination of any coverage issues other than whether health care services are or were medically necessary.^{xxiv}

In 2009, New York expanded the system to allow review of "out of network" denials where the issue is whether a service available out of a managed care plan's network materially differs from what is available in-network.^{xxv} That expansion, however, appears insufficient to meet the scope of review required by the ACA. New York will have to entertain all questions regarding "level of care, appropriateness, effectiveness, and health care setting" Thus, disputes over access to particular specialists, which have heretofore not been entertained by the external review system, will thereafter be able to be addressed in the system. The exclusions from the category of utilization review recited above will have to be repealed or modified to ensure that all disputes regarding setting and level of care, including disputes over use of particular network providers are subject to external review.

Discussions with Insurance Department personnel suggest that it is seeking written guidance from the federal government on the necessity of this change. Inquiry to another state (Virginia) which currently uses language similar to the NAIC Uniform Model Act in its external review statute and to Ellen Kuhn, Director of Appeals, Office of Consumer Support, Department of Health and Human Services, in preparing this report^{xxvi} confirms that use of the NAIC Uniform Model Act language would bring such disputes within the scope of external review. Ms. Kuhn confirmed that disputes over treatment by a particular type of specialist (e.g. breast surgeon vs. general surgeon for a mastectomy) and regarding the choice of a particular specialist with particular expertise (e.g. treatment in a specialized soft tissue cancer program vs. treatment by a general oncologist with limited experience in that particular low incidence cancer) would be interpreted as issues of health care setting.

In expanding the scope of the questions subject to external review to matters such as choice of specialists and access to out of network care, New York would have to choose a standard by which to judge such disputes. It has a ready model in existing law regarding access to procedures which are only available out of network – whether the treatment sought from a particular specialist or out of network provider would lead to a materially different health outcome than the available in-network alternatives. With respect to other matters that have to

IMPLEMENTING HEALTH CARE REFORM: EXTERNAL REVIEW OF HEALTH PLAN DECISIONS

do with health care setting and level of care, including coding disputes and what category of care a particular treatment falls under, the standard can be that of prevailing standards in the pertinent medical field.

III. WHAT ADDITIONAL CHANGES MAY THE STATE CONTEMPLATE IN THE PROCESS OF ENACTING CONFORMING LEGISLATION?

As the above changes are enacted in order to keep New York's external review system operative, the State must consider whether to make other changes that could significantly strengthen the system. New York could increase the number of users of the system, and generate revenue for its operation, by requiring multi-employer welfare arrangements to participate in it, and by making the system available for use by large self-insured plans. It could also make administration easier for regulators and navigation easier for consumers and those who assist them by subjecting grandfathered and non-grandfathered plans alike to the new external review rules, even though federal law would only require non-grandfathered plans to comply with them.

Additionally, the State should be looking ahead as it enacts its changes to future needs. New York already has specific rules in its external review system for decisions regarding access to clinical trials. Those rules could be changed now to conform to the ACA's rules regarding access to clinical trials which will go into effect in 2014. Further, the State could put in place a process for evaluating additional issues that may subject to review in the external review system.

A. Opening External Review to Multi-Employer Welfare Arrangements and Self-Insured Plans

The authority for operation of New York's current external review system is found in Article 49 of the Insurance Law and parallel provisions in Article 49 of the Public Health Law, which address both internal utilization review and external review of utilization review decisions. The law covers "health care plans" which are defined as "an insurer subject to article thirty-two or forty-three of [the insurance law]... or any organization licensed under article forty-three of [the insurance law]..." (Insurance Law. §4900(d-5)), or "any organization certified under article forty-four" of the Public Health Law, i.e. licensed Health Maintenance Organizations (Pub. Health L. §4900 4-e). Insurance Law §4908 currently provides that Article 49 "shall not apply to any utilization review conducted by, or on behalf of, a self-insured employee welfare benefit plan, as defined in the employee retirement income security act of 1974, as amended." Public Health Law §4908 contains a parallel exemption.

The State has appropriately refrained from trying to regulate self-insured health plans, as reflected in the external review statute, because of long-standing legal precedent establishing that a federal law, ERISA, preempts any attempt at such regulation. Indeed, when the State Insurance Department did publish data on the reasons for requests for review being deemed ineligible for processing, one of the largest groups of rejected applications involved claims under self-insured plans.

The ACA, however, now imposes external review requirements on all health plans, whether insured or not and whether subject to state regulation or not. Federal regulators, recognizing that state external review systems are in most states already up and running, appear to be encouraging states to extend their external review systems as broadly as possible.^{xxvii} The logic of that position would seem to open the door to ERISA governed self-insured plans voluntarily opting to use state systems of states that permit them to do so, and in later guidance, cited below, the federal government has recognized that possibility. This presents New York with several decisions:

IMPLEMENTING HEALTH CARE REFORM: EXTERNAL REVIEW OF HEALTH PLAN DECISIONS

(i) Non-ERISA preempted self-insured plans As the Interim Final Rules point out, states already have the authority to subject certain self-insured plans to state regulation. These include including self-insured religious organizations, self-insured government plans (other than federal government plans), and multiemployer welfare arrangements (MEWAs).

New York has already incorporated its municipal cooperative health benefit plans into the external review system. Those plans are subject to various consumer protections by Article 47 of the Insurance Law. As to other self-insured non-ERISA preempted plans, such as church plans and MEWAs, the State has not been an aggressive regulator of such plans in the past, but in a world of more universal coverage in which everyone is required to have coverage meeting certain minimum standards, the argument becomes much more compelling to extend the uniformity of remedies and standards as well, and to more aggressively and comprehensively regulate such plans as part of the universe of coverage. Inclusion of these plans in the external review system could be the first step in that direction, and the numbers of enrollees are such that they are unlikely to burden the system.

(ii) Self-insured ERISA plans: HHS has recognized the possibility that States could open their external review systems to voluntary use by ERISA exempt plans, as those plans would in any event have to comply with federal external review requirements and might have various reasons, including simply convenience in using a system already at hand, to participate in an existing, well-run state system:

Voluntary compliance with State external review processes.

... States may choose to expand access to their State external review process to plans that are not subject to the applicable State laws, such as self-insured plans, and such plans may choose to voluntarily comply with the provisions of that State external review process.^{xxviii}

Extending the external review system to ERISA exempt self-insured plans would potentially expand the demand for the state's external review services substantially. The most credible estimates are that more than 20% of the total population of the state, over 4,000,000 people, are enrolled in self-insured plans,^{xxix} and the bulk of these enrollees are undoubtedly in large ERISA-exempt plans. In the unlikely event all self-insured plans covering consumers in the state were to take advantage of state external review for their New York members, this would represent at least a 40% increase in the number of consumers eligible to take advantage of external review.

Such a large expansion would seem unlikely. Many national plans already have their own external review systems, which may comply or be easily modified to comply with the federal external review system to be established. Other national plans might fear the consequences of their members in different states obtaining different coverage decisions from different state external review systems with differing standards.

In determining whether to invite ERISA-exempt self-insured plans to use the state system, the State will have to assess the capacity of the current system to accommodate the estimated number of new users, both from the standpoint of internal Insurance Department personnel and of the current vendors performing the external reviews. In making that determination, it should take into account the potential receipt of user fees to be charged to the self-insured plans, and whether those fees might, indeed, help defray the cost of maintaining the current system and keeping it running in its current efficient and responsive way. The State should take into account the advantages of having a much larger pool of New Yorkers participate in a single system of

IMPLEMENTING HEALTH CARE REFORM: EXTERNAL REVIEW OF HEALTH PLAN DECISIONS

review with a single standard of medical decision-making, meaning that uniformity and predictability of coverage are enhanced both for consumers and medical practitioners.

B. Grandfathered vs. Non-Grandfathered Plans

The ACA does not apply the new rules for external review to “grandfathered” health plans, those in existence when the law passed on March 23, 2010, and which have not undergone substantial change after that date. An employer could, under amendments to the Interim Final Rules promulgated with respect to grandfathering, purchase a new insurance policy from a new insurer without sacrificing grandfathered status, but if that new policy differed in significant respects from the previous policy, such as by dropping coverage for particular treatment modalities or conditions or significantly changing cost sharing arrangements, it would not retain grandfathered status.^{xxx} Theoretically, New York could comply with the ACA by changing its external review rules only for policies which do not have grandfathered status, and retaining current rules for the grandfathered plans.

Though a two-tiered external review system would be valid and compliant with the ACA, it would be a very poor policy alternative. It would add administrative complexity to the system, because the Insurance Department would for each filed external review have to ascertain the grandfathered or non-grandfathered status of the health plan in question. Similarly situated consumers, covered by the exact same insurance policies, could be covered by different sets of rules based simply on when they or their employers first purchased the policies, and examination of a policy on its face would not tell the consumer, or any consumer assistance program or attorney assisting the consumer, whether or not the plan is a grandfathered one. Public education of consumers about enforcing their rights would become more difficult; even regarding so basic a matter as the deadline for filing an external review (45 days from a final adverse decision under current New York law, 4 months under the ACA).

Insurers, too, would find life considerably more complex under a bifurcated system. They are required to describe external review rights to their policyholders and group members in summary plan descriptions and similar documents. They would have to have two different sets of such plan documents for a single policy form, one set for those who hold that policy form as a grandfathered plan and another for those who bought the identical policy after March 23, 2010. Insurers’ customer service personnel would have to in each instance ascertain the grandfathered status of a member’s policy before answering questions. It is not too difficult to imagine that many consumers who should be governed by one set of rules are likely, inadvertently or otherwise, to end up having their claims decided under a different set of rules.

Perhaps most important, the provisions of the ACA with which New York is required to conform are those which are more consumer protective than our current law. Providing a longer time to prepare the external review request, lowering the filing fee, allowing consumers who are not dying or severely disabled to obtain external review of experimental treatment denials are all positive reforms which we should welcome as increasing consumer protection. Just because the federal government has not seen fit to compel extending all these protections to consumers in grandfathered plans is not a reason for New York to create a two-tiered system of health justice based on a factor as trivial as the date on which a policy was first purchased.

IMPLEMENTING HEALTH CARE REFORM: EXTERNAL REVIEW OF HEALTH PLAN DECISIONS

C. Standards for Access to Clinical Trials

The new federal standards regarding external review do not refer specifically to treatments in clinical trials. The ACA's mandate for coverage of clinical trials for people with cancer or other life threatening conditions^{xxxi} does not go into effect until 2014. However, because New York's clinical trial rules are included in its external review law, it could, when passing other conforming provisions with respect to external review this year, anticipate the new federal requirements, to the extent that they exceed the current New York protections, and enact now as well. In particular, the federal mandate will be for coverage of Phase I, II, III and IV clinical trials, without any independent showing, as required by New York now, that the treatment is likely to provide benefit to the patient. New York's current requirement to show likely benefit could be read to exclude coverage of some Phase I clinical trials, although there are strong public policy reasons to encourage patient enrollment in such trials in order to improve medical treatments for all.

Accordingly, New York's test for clinical trial coverage should be amended to provide that a person with a life threatening or seriously disabling illness should be approved for any Phase I, II, III or IV clinical trial which he or she is qualified to enter into for treatment of that condition. The requirement to show likely benefit to the patient enrolled in a clinical trial should be repealed in order to recognize that some legitimate clinical trials, particularly Phase I clinical trials, are conducted to assess matters such as safety and toxicity of the treatment. Tests of likely benefit only come in later stage trials, and the new federal standards recognize this.

D. Other disputed health plan decisions

While the ACA does not mandate it broadening external review to all categories of consumer disputes with their health plans, New York should recognize that there are many types of decisions which might be better and more economically decided, with far less cost to the health system, by a mechanism like external review. External review by medical experts would seem particularly appropriate for disputes involving the exercise of medical judgment.

New York has experienced a steady growth in applications for use of the external review system. In part this certainly reflects the liberalized rules under which providers may request review.^{xxxii} But with that growth has come an even faster growth in rejections of requests for review as ineligible for review. Annual reports of the Insurance Department's operations to the Governor reflect that from 2006 to 2009, the proportion of submitted external review requests which were rejected as ineligible rose from 27.5% to 41.8%:

Year	Appeals submitted	Appeals rejected	% rejected
2006	2858	787	27.50%
2007	2987	887	29.70%
2008	3920	1566	39.90%
2009	4260	2033	41.80%

The disproportionate increase in rejection of submitted claims is disturbing, but it is difficult for members of the public to know why the increase has taken place, because the Insurance Department has not published a detailed external review system report since the one for calendar year 2005. In that report, which did enumerate the principle reasons for ineligibility, the leading causes were late filing, incomplete applications, failure to exhaust administrative remedies, not being an authorized person to file a request, and being covered by self-insured plans. But there were a few persistent areas of subject matter ineligibility. These included

IMPLEMENTING HEALTH CARE REFORM: EXTERNAL REVIEW OF HEALTH PLAN DECISIONS

disputes over seeing nonparticipating providers, claims for benefits simply that were not covered benefits under a policy, and coding disputes.

While ACA compliance should bring some of these issues into the external review system, it is not clear that all coding questions, which involve areas of knowledge that are particularly difficult for consumers to approach, will be encompassed. The recent creation of FairHealth, an external agency to establish fair pricing data for insurance disputes about usual, customary and reasonable rates, under a consent decree between the industry and the New York Attorney General's office,^{xxxiii} will only go part of the way to resolving disputes over the amounts consumers are reimbursed. Given the apparent level of consumer demand for impartial assistance in resolving disputes over reimbursement levels, this area would seem a prime one for adding to the scope of questions reviewed in external review.

There are certainly other issues which involve the application of medical judgment that could easily be added to the external review system without burdening the system. These would include disputes over such matters as application of pre-existing condition limitations and judgments regarding whether a person is totally disabled for purposes of continuing health plan benefits. That the Insurance Department did not report any significant number of such requests that it denied, when it last reported numbers, suggests that these categories too, and indeed all decisions involving the exercise of medical judgment, could be added to the external review system without burden on the system. Because the issues involve application of medical expertise, they should also be able to use the current infrastructure of IROs.

While it may be appropriate to defer expansions to these issues pending an analysis of the effects of the mandatory ACA changes and other recommended changes discussed above, it is not too soon to put in place a process for determining which additional types of disputes might be appropriate for external review. Study of the experience generated by consumer assistance programs, already operating in New York with federal assistance, should be considered as a way of determining which other types of disputes might most benefit from incorporation into the external review system.

CONCLUSION

New York must enact legislation to have the reforms to its external review system outlined above in place before July 1, 2011. The underlying policies which should guide the reforms are maintenance of the right to use New York's current system by enacting all the mandatory changes, together with extension of the system to the broadest population possible, in the most equal manner possible, and with a view to future changes that will benefit consumers and insurers through access to inexpensive and fair dispute resolution mechanisms.

IMPLEMENTING HEALTH CARE REFORM: EXTERNAL REVIEW OF HEALTH PLAN DECISIONS

APPENDIX

For a State external review process to apply instead of the Federal external review process, the Affordable Care Act provides that the State external review process must include, at a minimum, the consumer protections of the NAIC Uniform Model Act. Accordingly, the Departments have determined that the following elements from the NAIC Uniform Model Act are the minimum consumer protections that must be included for a State external review process to apply.

The State process must:

- Provide for the external review of adverse benefit determinations (and final internal adverse benefit determinations) that are based on medical necessity, appropriateness, health care setting, level of care, or effectiveness of a covered benefit.
- Require issuers to provide effective written notice to claimants of their rights in connection with an external review for an adverse benefit determination.
- To the extent the State process requires exhaustion of an internal claims and appeals process, make exhaustion unnecessary if: the issuer has waived the exhaustion requirement, the claimant has exhausted (or is considered to have exhausted) the internal claims and appeals process under applicable law, or the claimant has applied for expedited external review at the same time as applying for an expedited internal appeal.
- Provide that the issuer against which a request for external review is filed must pay the cost of an independent review organization (IRO) for conducting the external review. While having the issuer pay the cost of the IRO's review is reflected in the NAIC Uniform Model Act, if the State pays this cost, the Departments would treat the State process as meeting this requirement; this alternative is just as protective to the consumer because the cost of the review is not imposed on the consumer. Notwithstanding this requirement that the issuer (or State) must pay the cost of the IRO's review, the State process may require a nominal filing fee from the claimant requesting an external review. For this purpose, to be considered nominal, a filing fee must not exceed \$25, it must be refunded to the claimant if the adverse benefit determination is reversed through external review, it must be waived if payment of the fee would impose an undue financial hardship, and the annual limit on filing fees for any claimant within a single year must not exceed \$75.
- Not impose a restriction on the minimum dollar amount of a claim for it to be eligible for external review (for example, a \$500 minimum claims threshold).
- Allow at least four months after the receipt of a notice of an adverse benefit determination or final internal adverse benefit determination for a request for an external review to be filed.
- Provide that an IRO will be assigned on a random basis or another method of assignment that assures the independence and impartiality of the assignment process (for example, rotational assignment) by a State or independent entity, and in no event selected by the issuer, plan, or individual.
- Provide for maintenance of a list of approved IROs qualified to conduct the review based on the nature of the health care service that is the subject of the review. The State process must provide for approval only of IROs that are accredited by a nationally recognized private accrediting organization.

IMPLEMENTING HEALTH CARE REFORM: EXTERNAL REVIEW OF HEALTH PLAN DECISIONS

- Provide that any approved IRO has no conflicts of interest that will influence its independence.
- Allow the claimant to submit to the IRO in writing additional information that the IRO must consider when conducting the external review and require that the claimant is notified of such right to do so. The process must also require that any additional information submitted by the claimant to the IRO must be forwarded to the issuer within one business day of receipt by the IRO.
- Provide that the decision is binding on the plan or issuer, as well as the claimant, except to the extent that other remedies are available under State or Federal law.
- Provide that, for standard external review, within no more than 45 days after the receipt of the request for external review by the IRO, the IRO must provide written notice to the issuer and the claimant of its decision to uphold or reverse the adverse benefit determination.
- Provide for an expedited external review in certain circumstances and, in such cases, the State process must provide notice of the decision as expeditiously as possible, but not later than 72 hours after the receipt of the request.
- Require that issuers include a description of the external review process in the summary plan description, policy, certificate, membership booklet, outline of coverage, or other evidence of coverage it provides to claimants, substantially similar to what is set forth in section 17 of the NAIC Uniform Model Act.
- Require that IROs maintain written records and make them available upon request to the State, substantially similar to what is set forth in section 15 of the NAIC Uniform Model Act.
- Follow procedures for external review of adverse benefit determinations involving experimental or investigational treatment, substantially similar to what is set forth in section 10 of the NAIC Uniform Model Act.

75 Fed Reg. at 43335 (July 23, 2010)

IMPLEMENTING HEALTH CARE REFORM: EXTERNAL REVIEW OF HEALTH PLAN DECISIONS

ENDNOTES

- ⁱ “key consumer protections [include] the right to a true external appeal of a health plan denial of care”, Testimony of Ronald Pollack, Executive Director, Families USA, regarding S.283, the Bipartisan Patient Protection Act of 2001, available at <http://www.stanford.edu/class/siw198q/websites/HearingMar01/patient.html>
- ⁱⁱ “External review programs continue to serve the interests of both consumers and health insurance plans by providing a way to resolve coverage disputes in a fair, timely and less costly manner than through the courts.” AHIP Center for Policy and Research, Update on State External Review Programs (January 2006), available at http://www.ahipresearch.org/pdfs/External_ReviewJan06.pdf
- ⁱⁱⁱ “External review has been widely recognized as an important consumer protection, providing a way for disputes between health plans and consumers to be resolved fairly, expeditiously and relatively inexpensively.” K. Pollitz, J. Crowley, K. Lucia, E. Bangit, Assessing State External Review Programs and the Effects of Pending Federal Patients’ Rights Legislation, Kaiser Family Foundation, rev’d 2002, available at <http://www.kff.org/insurance/externalreviewpart2rev.pdf>
- ^{iv}“ K. Pollitz, G. Dallek and N. Tapay, “External Review of Health Plan Decisions: An Overview of Key Program Features in the States and Medicare” Prepared for the Kaiser Family Foundation, available at http://www.kff.org/insurance/1443-review_r.cfm. “Patients will find it easier to appeal denials” web posting July 23, 2010 by Patient Advocate Foundation, <http://www.patientadvocate.org/news.php?p=811>
- ^v Update on State External Review Programs, supra note ii, at Appendix A and B.
- ^{vi} *Nenno v. Blue Cross and Blue Shield*, 303 A.D.2d 930, 757 N.Y.S.2d 165, lv to appeal denied, 306 A.D.2d 960, 760 N.Y.S.2d 70 (4th Dept. 2003)
- ^{vii} Update on State External Review Programs (January 2006), supra note ii, at p. 4
- ^{viii} Pub. L. 111-148 (March 23, 2010)
- ^{ix} Extensive regulations have been issued interpreting what sorts of changes in an existing plan will cause it to lose “grandfathered” status. See <http://www.hhs.gov/ociio/regulations/grandfather/index.html>
- ^x Insurance Department, Opinions of General Counsel, Opinion Number 04-05-15
- ^{xi} http://www.naic.org/index_about.htm
- ^{xii} http://www.naic.org/documents/committees_b_uniform_health_carrier_ext_rev_model_act.pdf
- ^{xiii} A “plan year” begins on the anniversary date of the coverage for an employer, when it renews its coverage or purchases different coverage
- ^{xiv} Some aspects of that interim final rule have been modified. Technical Release No. 2011-01 Extension of Non-Enforcement Period Relating to Certain Interim Procedures for Internal Claims and Appeals under the Patient Protection and Affordable Care Act, March 18, 2011 <http://www.dol.gov/ebsa/newsroom/tr11-01.html>, issued by the ebsa.. The provisions regarding state standards for external review have, except for one change discussed in the body of this report, not been disturbed.
- ^{xv} “Interim Final Rules for Group Health Plans and Health Insurance Issuers Relating to Internal Claims and Appeals and External Review Processes Under the Patient Protection and Affordable Care Act; Interim Final Rule [7/23/2010]

IMPLEMENTING HEALTH CARE REFORM: EXTERNAL REVIEW OF HEALTH PLAN DECISIONS

[Federal Register: July 23, 2010 (Volume 75, Number 141)]

[Page 43329-43364],

<http://webapps.dol.gov/FederalRegister/HtmlDisplay.aspx?DocId=24056&AgencyId=8&DocumentType=2>

^{xvi} “The preemption provisions of ERISA section 731 and PHS Act section 2724 (implemented in 29 CFR 2590.731(a) and 45 CFR 146.143(a)) apply so that the requirements of part 7 of ERISA and title XXVII of the PHS Act, as amended by the Affordable Care Act, are not to be construed to supersede any provision of State law which establishes, implements, or continues in effect any standard or requirement solely relating to health insurance issuers in connection with group or individual health insurance coverage except to the extent that such standard or requirement prevents the application of a requirement” of the Affordable Care Act. Accordingly, State laws that impose on health insurance issuers requirements that are stricter than those imposed by the Affordable Care Act will not be superseded by the Affordable Care Act.” Interim Final Rules, *supra* note xv, 75 F.R. at 43331 July 23, 2010

^{xvii} The grace period for compliance and the consequences of noncompliance are set forth in the Interim Final Rules:

“In order to allow States time to amend their laws to meet or go beyond the minimum consumer protections of the NAIC Uniform Model Act set forth in these interim final regulations, the Departments are using their authority under PHS Act section 2719(c) to treat existing State external review processes as meeting the minimum standards during a transition period for plan years (in the individual market, policy years) beginning before July 1, 2011. Thus, for plan or policy years beginning before July 1, 2011, a health insurance issuer subject to an existing State external review process must comply with that State external review process and not the Federal external review process. The applicable external review process for plan or policy years beginning on or after July 1, 2011 depends on the type of coverage and whether the State external review process has been determined by the Department of Health and Human Services to satisfy the minimum standards of the NAIC Uniform Model Act.” Interim Final Rules, *supra* note xv, 75 F.R. at 43336

^{xviii} 11 N.Y.C.R.R. §410.13, 10 N.Y.C.R.R. §98-2.12

^{xix} “In the case of a plan or issuer that fails to strictly adhere to all the requirements of this paragraph (b)(2) with respect to a claim, the claimant is deemed to have exhausted the internal claims and appeals process of this paragraph (b), regardless of whether the plan or issuer asserts that it substantially complied.” 26 C.F.R. §54.9815-2719T(b)(2)(ii)(F); 29 C.F.R. 2590.715-2719 (b)(2)(ii)(F); 45 C.F.R. §147.136(b)(2)(ii)(F)

^{xx} Ins. L. §4903(g): “Failure by the utilization review agent to make a determination within the time periods prescribed in this section shall be deemed to be an adverse determination subject to appeal pursuant to section four thousand nine hundred four of this title”

Ins. L. §4904 (e): “Failure by the utilization review agent to make a determination within the applicable time periods in this section shall be deemed to be a reversal of the utilization review agent's adverse determination..”

^{xxi} 26 C.F.R. §54.9815-2719T(c)(2)(xi); 29 C.F.R. 2590.715-2719 (c)(2)(xi); 45 C.F.R. §147.136(c)(2)(xi)

^{xxii} NAIC Uniform Model Act §9, incorporated by reference in the Interim Final Rules

^{xxiii} Involving hospital charges paid on a “charge basis” rather than on the basis of the diagnosis for which the patient was treated

^{xxiv} Insurance Law §4900 (h), Public Health Law §4900.8

^{xxv} New York’s system already includes insured indemnity health plans and is not restricted to HMOs or other managed care organizations. New York need not confront, therefore, the possibility that its entire

IMPLEMENTING HEALTH CARE REFORM: EXTERNAL REVIEW OF HEALTH PLAN DECISIONS

external review system might be deemed invalid for plan or policy years beginning on and after July 12, 2011. The Interim Final Rule reserved this question for future resolution (75 F.R. 43336), and discussions with HHS suggest that the federal government's position still has not been arrived at.

^{xxvi} Telephone interview, November 12, 2010

^{xxvii} “The Departments encourage States to establish external review processes that meet the minimum consumer protections of the NAIC Uniform Model Act. The Departments prefer having States take the lead role in regulating health insurance issuers, with Federal enforcement only as a fallback measure.” To that end, the federal government encourages states to subject non-ERISA preempted self insured group plans to state regulation: These interim final regulations do not preclude a State external review process from applying to and being binding on a self-insured group health plan under some circumstances. While the preemption provisions of ERISA ordinarily would prevent a State external review process from applying directly to an ERISA plan, ERISA preemption does not prevent a State external review process from applying to some self-insured plans, such as nonfederal governmental plans and church plans not covered by ERISA preemption, and multiple employer welfare arrangements, which can be subject to both ERISA and State insurance laws. A State external review process could apply to such plans if the process includes, at a minimum, the consumer protections in the NAIC Uniform Model Act.” Interim Final Rules, *supra* note xi, 75 F.R. at 43335.

^{xxviii} Availability of Interim Procedures for Federal External Review and Model Notices Relating to Internal Claims and Appeals and External Review Under the Patient Protection and Affordable Care Act; Notice [8/26/2010] [Federal Register: August 26, 2010 (Volume 75, Number 165)], Page 52597, at 52598 <http://webapps.dol.gov/federalregister/HtmlDisplay.aspx?DocId=24179&AgencyId=8&DocumentType=3>, last visited Jan. 12, 2011.

^{xxix} Newell and Baumgarten, “The Big Picture: Private and Public Health Insurance Markets in New York” (United Hospital Fund 2009) at 77-78, based on AHRQ and State Department of Health estimates from 2005-2006

^{xxx} See, Group Health Plans and Health Insurance Coverage Relating to Status as a Grandfathered Health Plan Under the Patient Protection and Affordable Care Act; Interim Final Rule and Proposed Rule, Federal Register: June 17, 2010 (Volume 75, Number 116), Page 34537-34570, and Amendment to the Interim Final Rules for Group Health Plans and Health Insurance Coverage Relating to Status as a Grandfathered Health Plan Under the Patient Protection and Affordable Care Act, Federal Register: November 17, 2010 (Volume 75, Number 221), Page 70114-70122

^{xxxi} Affordable Care Act §10103(c), Public Health Service Act §2709

^{xxxii} *Ibid*

^{xxxiii} <http://fairhealthus.org/>