September 21, 2010

Secretary Timothy Geithner
Department of the Treasury

Secretary Hilda Solis
Department of Labor

Secretary Kathleen Sebelius
Department of Health and Human Services
Office of Consumer Information and Insurance Oversight
Department of Health and Human Services
Attention: OCIIO-9993-IFC
P.O. Box 8016
Baltimore, MD 21244-1850

Dear Secretary Sebelius:

Health Care for All New York (HCFANY) writes to comment on the interim final rules 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 (PPACA). HCFANY is a statewide coalition of more than 100 organizations, which seek to achieve affordable, quality health care for all New Yorkers.

Overall, we commend the Department for developing regulations that provide strong consumer protections. In particular, we are pleased that the guidance will allow New York State to open its external review process to self-insured plans and self-insured plans can subject themselves to that process as a way of complying. New York has a highly successful external review program, and is very well run by the State Department of Insurance. Advocates have worked to expand the scope of the program to more decisions, as PPACA will now allow, and also support the availability of the process to consumers in self-insured plans.

We have some recommendations for ways that the rules could be make clearer or stronger, in the following areas: adverse benefit determination; notice and information issues; qualifications of reviewers; standards of review; language and literacy issues; informing...
consumers about their right to consumer assistance and advocacy; legal remedies; and the minimum standards for consumer protection in the NAIC model act.

**Adverse Benefit Determinations**

The interim final rule does not clearly state that any adverse benefit determination eligible for internal review is also eligible for external review. The rules should also be amended to include the denial of access to a specialist provider by a plan in the list of adverse benefit determinations which can be appealed. The Department should clarify how consumers can complain if other rights under PPACA are violated, and require plans to share this information with consumers. The rules should be clarified to indicate that rescissions of coverage are eligible for external review under State processes.

First, as mentioned above, we recommend that the Department add the denial of access to a specialist provider—even if it is an out-of-network provider—by a plan or issuer to the enumerated list of adverse benefit determinations which can be appealed through the internal and external appeal processes. In some cases, there are uniquely qualified specialists, centers of excellence and so forth, with the capacity to treat a certain condition. In these cases, a denial of access to a specific doctor or provider can be tantamount to denial to a type of medically necessary treatment in its entirety.

We recommend that the Department clarify how consumers can complain when they believe that a plan or issuer has made a decision that violates one of PPACA’s new consumer protection provisions, like whether a plan meets the grandfathering criteria, or whether a young person is eligible for dependent coverage. The Department should release clear information about how consumers can contest these decisions, and require health plans and insurers to inform consumers as well.

Finally, the definition of adverse benefit determination for both internal and external review in the rule includes rescissions of coverage (§54.9815-2719T(a)(2)(a)). The section of the rules relating to internal claims and appeals specifies that a rescission of coverage must be treated as an adverse benefit determination (§54.9815-2719T(b)(2)(a)) and the section of the rules relating to the federal external appeals process refers to the definition found at §54.9815-2719T(a)(2)(a). However, the section of the rules relating to State external review processes lists decisions that can be reviewed, and does not include rescissions of coverage in this list (§54.9815-2719T(c)(2)(i)). The Department should correct this oversight to clarify that all adverse benefit decisions subject to internal review are also subject to the State external review process.

**Notice and Information Issues**

We commend the Department for developing rules with strong protections for consumers in the notice requirements. The model notices are well designed, and we are pleased to see that they include contact information for Consumer Assistance Programs. However, we recommend
that the rules require that the plan or issuer provide consumers with more information in these notices. We also recommend that the rules require a plan or issuer to provide a consumer with a copy of the file that is provided to the IRO, with time for the consumer to respond. Finally, we recommend that IROs or State agencies making external review determinations report the substance of their decisions so that consumers can see how similar disputes have been resolved.

The rules require an insurer or plan to include in the notice the reason or reasons for the adverse benefit determination, including a denial code, its meaning, a description of the standard, if any, used in the decision, and in the case of a final internal adverse determination, a discussion of the decision. We recommend that the consumers should also be provided with any guidelines of the plan or issuer relating to the subject matter of the dispute, regardless of whether they were relied upon in the determination.

Additionally, consumers should be given a copy of any materials submitted by the plan or issuer to the IRO for consideration in the external review. The plan or issuer should send a copy of the file to the consumer at the same time that it sends a copy to the IRO. The consumer should have 5 days to review the file and respond with evidence.

We also recommend that the rules require a State agency or IRO making an external appeal determination to report the substance of each decision, in a redacted format to protect consumer privacy, in a way that allows a consumer with an issue to appeal to research how similar disputes have been resolved.

Qualifications of reviewers

We commend the Department for making it clear that Independent Review Organizations (IRO) used in State or federal external review processes must be accredited and follow clear standards to prevent conflicts of interest. These rules will greatly increase consumer confidence in the review process and produce fairer outcomes. The Department could improve on the rules, however, by ensuring that review of legal issues is performed by reviewers with legal expertise, and that reviewers of medical issues are experts in the particular field of medicine at issue.

Some decisions that will be presented for review by IROs are legal issues. For example, a case might present questions about whether a plan issuer has complied with State or federal law. IROs typically employ reviewers with clinical expertise, to review medical questions, but not legal expertise. While the technical guidance issued by the Departments of Labor and Health and Human Services regarding interim procedures for federal external review in the group and individual markets require external reviews to be conducted by reviewers with legal and clinical expertise,¹ the interim final rules do not indicate that IROs employed in State review must have legal experience. To ensure that these questions receive appropriate review, the Department should direct cases with legal issues to State or federal regulatory agencies, or require IROs to employ reviewers with legal expertise.
We also recommend that the Department include strict standards for medical reviewers employed in external reviews, similar to the standard found in the NAIC Model Act. The act specifies that the reviewer must be an expert in the treatment of the covered person’s medical condition that is the subject of the external review, and must be knowledgeable about the recommended health care service or treatment through recent or current actual clinical experience treating patients with the same or similar medical condition.

**Standards of Review**

We urge the Department to clarify that a State external review process must provide for de novo review of adverse benefits decisions. Additionally, the external reviewer should be able to consider the best interest of the consumer in making a determination.

The NAIC Uniform Health Carrier External Review Model Act specifies that “the assigned independent review organization is not bound by any decisions or conclusions reached during the health carrier’s utilization review process . . . or the health carrier’s internal grievance process . . .” Similarly, the technical guidance issued by the Departments of Labor and Health and Human Services regarding interim procedures for federal external review in the group and individual markets state that an examiner will “review the claim de novo and not be bound by any decisions or conclusions reached during the plan’s [health insurance issuer’s] internal claims and appeals process” in reaching a decision.

We assume that the Department’s requirement that a State external review process provide at a minimum the consumer protections of the NAIC Uniform Model Act includes the de novo standard. We urge the Department to make this requirement explicit through further guidance.

Additionally, the reviewer should be allowed to consider the best interest of the consumer in making a determination. New York State’s statute requires that an “external appeal agent shall review the utilization review agent's final adverse determination and, in accordance with the provisions of this title, shall make a determination as to whether the health care plan acted reasonably and with sound medical judgment and in the best interest of the patient.”

**Language and Literacy Issues**

**Notice Thresholds**

We commend the Department for requiring plans and issuers to provide notices in languages other than English, but we recommend that the Department lower the thresholds for determining whether a plan or issuer must provide written appeals notices in languages other than English.

The interim final rule requires plans and issuers to provide notices in languages other than English according to thresholds, based on the number of participants in the plan. If a plan
covers fewer than 100 participants at the beginning of a plan year, it must provide notices in a language other than English if 25 percent of all plan participants are literate only in that language. If a plan covers more than 100 participants at the beginning of the plan year, it must provide notices in a language other than English if the lesser of 500 participants, or 10 percent of all plan participants, are literate only in that language. In the individual market, a plan must provide notices in a language other than English if 10 percent of the households in the county are literate only in that language.

We are concerned that these thresholds are too high. In the United States, 8.6 percent of people age 5 and over speak English less than “very well,” a level of proficiency that may be required to understand a notice of appeal. The language used in notices and other correspondence relating to appeals is highly technical, and difficult for consumers to understand even in their first language. Appeals are time-sensitive, and consumers who need translation could miss an opportunity to appeal a critical decision because they were unable to find help reading the notice in time. Almost five percent of households in the United States are “linguistically isolated” – no member of the household 14 years old or older speaks only English or speaks English “very well.” For these households, finding a translator in time to appeal a decision would be very challenging. This issue is even more likely to affect New York consumers: over 13 percent of New Yorkers aged 5 and over speak English less than “very well,” and 8.4 percent of New York households are linguistically isolated.

We recommend that the Department instead adopt the standard used by New York State in its Hospital Financial Assistance Law. This law requires hospitals to print applications for financial assistance in the primary languages of patients served by the hospital. The hospital must determine these primary languages by reviewing two factors: the languages used to communicate with patients who receive services from the hospital, and the languages spoken by consumers living in the hospital’s primary service area. A hospital is required to provide applications in a language other than English if it is “used to communicate, during at least five percent of patient visits in a year, by patients who cannot speak, read, write or understand the English language at the level of proficiency necessary for effective communication with health care providers.” We recommend that the Department to lower the group market threshold to five percent of the plan participants, regardless of the number of plan participants.

The hospital financial assistance law also requires a hospital to provide applications in a language other than English if it is “spoken by non-English speaking individuals comprising more than one percent of the primary hospital service area population, as calculated using demographic information available from the United States Bureau of the Census, supplemented by data from school systems.” We recommend that the Department lower the individual market threshold from 10 percent to one percent.

Oral Communications
We recommend that the Department supplement these language access rules by requiring plans or issuers to provide oral translation of notices in languages other than English and notify consumers of the right to receive such translation.

Not all limited English proficiency consumers will be able to receive notices translated into the language in which they are literate, even with more generous thresholds. Plans and insurers could serve these consumers through oral translation of notices. Language lines that provide translation into many languages are easily accessed. We recommend that the Department create a model notice that free oral translation of appeals notices is available, translated into at least the 15 languages in which the Social Security Administration provides Medicare information, and require plans and insurers to include this model notice with appeals notices.

**Limited prose literacy**

We also recommend that the Department ensure that consumers with limited prose literacy receive appeals notices in plain language that is easily understood.

Millions of adults in the United States have basic or below basic prose literacy. Low literacy can be as much of a barrier to these consumers as a lack of English proficiency. We recommend that the Department review model notices to ensure that they can be understood by a consumer with a fifth-grade reading level, and that the Department require plans or issuers to provide all appeals materials written at the same level.

**Consumer assistance and representation**

We commend the Department for requiring plans or issuers to include in an appeals notices information about government agencies and consumer assistance programs or ombuds programs that can assist them with their appeals. We urge the Department to make the interim final rules more explicit about a consumer’s right to representation in an appeal.

Consumer Assistance Programs and Ombuds programs funded through PPACA are charged with helping consumers with internal and external appeals. Including the contact information for these groups in an appeal notice will make it much easier for consumers to access this assistance. The Department could make this assistance more effective still by requiring plans and issuers to provide Consumer Assistance Programs or Ombuds programs with contact information for plan representatives charged with working with these assistance programs. The model notices should also explain to consumers when their health care provider can ask as an authorized representative for the consumer in the appeals process.

**Legal remedies**

The interim final rules and technical guidance for interim procedures for the federal external review processes state that an external review decision is binding except to the extent that other remedies are available under State or Federal law. We believe that this language could
be made stronger, by stating explicitly that a consumer has the right to proceed directly to court to pursue available remedies, without a requirement that they exhaust the external review process before doing so. Additionally, we recommend that the Department clarify the consumer’s right to pursue additional remedies in court by clarifying that an external review decision is binding on a consumer "unless reversed by a court of competent jurisdiction."

While the interim final rules and technical guidance do not state that a consumer must complete the external review process before going to court, they do not make it clear that a consumer has the right to proceed to court without first undergoing the external review process. Under New York State law, a consumer has the option to pursue an external appeal before proceeding to court, but is not required to do so before seeking a legal remedy in court. The statute explicitly states that, “The rights and remedies conferred in this article upon insureds and health care providers shall be cumulative and in addition to and not in lieu of any other rights or remedies available under law.”

We recommend that the Department clarify in the interim final rules and technical guidance that a consumer is not required to seek an external review of an adverse benefit determination before pursuing remedies available under State or Federal law. We also recommend that the Department include a statement explaining this right to consumers in the model notices.

We also recommend that the Department include clearer language in the interim final rules and technical guidance regarding a consumer’s right to proceed to court to seek legal remedies following an adverse decision by an external reviewer. The rules and guidance state that a decision by an IRO is binding on the claimant except to the extent that other remedies are available under State or Federal law. We recommend that the Department replace this language with "binding unless reversed by a court of competent jurisdiction."

**NAIC minimum consumer protections**

The interim final rules designate a list of consumer protections found in the NAIC model act as the “minimum standards for State external review processes. We believe that the following consumer protections, also found in the NAIC model act, are also essential minimum standards that should be added to the regulations:

- Consumers have the right to file internal and external appeals simultaneously for expedited review
- The standard of external review is de novo
- A carrier must immediately act to implement a reviewer’s decision
- The IRO must consider medical records, attending professional’s recommendation, consultant reports, and practice guidelines in addition to carrier’s criteria
- Consumers have the right to be represented by someone the consumer has designated in writing
- Besides being accredited, an IRO must meet time frames for review; have qualified reviewers with relevant medical expertise and no conflicts of interest
and no disciplinary history; maintain confidentiality; and have a phone system capable of receiving information at all hours and instructing callers.

Thank you for considering our comments. If you have any questions, please contact Elisabeth Benjamin at ebenjamin@cssny.org or at (212) 614-5461 or Carrie Tracy at ctracy@cssny.org or at (212) 614-5401.

Sincerely,

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2 NAIC Uniform Health Carrier External Review Model Act Section 8(D)(2).


4 New York State Insurance Law § 4914(b)(4)(A).


8 New York State Public Health Law 2807-k(9-a)(e).

9 New York State Public Health Law 2807-k(9-a)(e). A hospital’s primary service area generally includes the county in which the hospital is located and all contiguous counties. The primary service area for a hospital in New York City includes the five counties that comprise New York City and any county contiguous to the county in which the hospital is located.

10 New York State Insurance Law §4907.