RE : **AETNA U.S. HEALTHCARE, INC.**	**)** **)** **)** **)** **)**	**CONSENT AGREEMENT** **Docket No. INS 00-3039**

This document is a Consent Agreement is authorized by 5 M.R.S.A. § 9053(2) and 24-A M.R.S.A. § 12-A(1), and is entered into by Aetna U.S. Healthcare, Inc. (hereafter also *Aetna*) and the Superintendent of the Maine Bureau of Insurance (hereafter also the *Superintendent*). Its purpose is to resolve, without resort to an adjudicatory proceeding, violations of 24-A M.R.S.A. § 4240, providing mandated coverage for diabetes supplies, and Maine Bureau of Insurance Rule Chapter 850(8), "Utilization Review," as set forth below.

FACTS

1. The Superintendent is the official charged with administering and enforcing Maine's insurance laws and regulations.
2. Since April 10, 1996, Aetna has been a Maine licensed health maintenance organization (HMO), License No. HMD45749.
3. Title 24-A M.R.S.A. § 4240, which became effective July 4,1996, mandates all HMOs to provide coverage and pay benefits for medically necessary diabetic supplies:

   All health maintenance individual and group health contracts must provide coverage for the medically appropriate and necessary equipment, limited to…insulin [and] syringes ... used to treat diabetes…..

4. Consumer, who has Type 1 diabetes and must inject insulin daily, is covered as a dependent under her father's Aetna group health plan. The coverage began on September 1, 1999. Before purchasing the Aetna plan through F, an independent insurance producer, Consumer's father told F he needed to know if the plan required Aetna to cover the cost of insulin cartridges. F assured Consumer's father the Aetna plan paid benefits for insulin cartridges, because of the law mandating coverage for diabetes supplies.
5. Even before the start of her Aetna plan, Consumer was using cartridges for injecting insulin. She had stopped using the traditional insulin delivery system, a glass vial and hypodermic needles, because for her cartridges are easier, faster, more precise as to dosage and can be administered in greater privacy than the hypodermic alternative, all of which gave Consumer a feeling of normalcy. Blood tests ordered at regular intervals by Consumer's treating endocrinologist, Dr. O, showed that her blood sugar levels using cartridges were comparable to normal, non-diabetic persons.
6. Shortly after September 1, 1999, Consumer's father telephoned Aetna to confirm that it would pay for Consumer's insulin cartridges when the prescription was filled. Rather than giving this confirmation, Aetna told her father that no diabetes supplies were

covered, purportedly because the group policyholder had not purchased a rider to augment the plan's drug benefits.

7. On September 8, 1999, F spoke with Aetna's Pharmacy Management office, and was told that the plan covered insulin but not devices for injecting the drug. In the next several days, after numerous follow-up calls and faxes to Aetna from Consumer's father and F, Aetna acknowledged that the Maine legislative mandate means insulin cartridges are covered by the plan, without the need for a rider. Aetna informed Consumer's father that under the plan, however, benefits for cartridges are payable only with its prior authorization based on a determination of medical necessity.
8. On September 15, 1999, Consumer presented to her pharmacy a prescription for diabetes supplies from Dr. O, her treating physician. The prescription was for NovoPen brand type H insulin cartridges. The pharmacist informed Consumer that Aetna's Pharmacy Management computer database, used by the pharmacy, indicated no plan coverage for diabetes supplies.
9. During the two weeks following the September 15th pharmacy episode, Consumer's father again contacted Aetna for coverage confirmation. On these occasions Aetna informed him that, although diabetes supplies were covered, Aetna would pre-authorize the cartridges only if medically necessary to Consumer. Consumer's father undertook to obtain Aetna's authorization. Near the end of September, Aetna telephoned Consumer's father informing him it denied authorization and that he could appeal the denial.
10. By letter dated September 30, 1999 addressed only to Dr. S, Consumer's primary care physician, but not to Consumer or her treating physician, Aetna denied authorization for the cartridges stating as its reason: "The cartridges are only approved for patients with physical or sight disabilities." Consumer and Dr. O first learned of the letter three months later during the Bureau's investigation of Consumer's complaint against Aetna. Dr. S denied ever receiving the letter.
11. In performing a utilization review of the medical necessity of Consumer's insulin cartridges, Aetna is subject to requirements of the Bureau's Rule 850(8), including:

    Rule 850(8)(E)(1) and (2) require that adverse utilization review decisions be in writing and be given to the covered person and the covered person's provider.

    Rule 850(8)(E)(5) requires all adverse utilization notices to include procedural disclosures:

    A written notice of an adverse determination shall include the principal reason or reasons for the determination, the instructions for initiating an appeal or reconsideration of the determination, and the instructions for requesting a written statement of the clinical rationale, including the clinical review criteria used to make the determination. The notification must include a phone number the covered person may call for information on and assistance with initiating an appeal or reconsideration and/or requesting clinical rationale and review criteria.

12. Aetna's adverse determination notice of September 30, 1999 was not sent to Consumer. The notice further did not contain instructions for requesting a written statement of the

clinical rationale for Aetna's decision, or a phone number to call for information and assistance in initiating an appeal or reconsideration.

13. On October 25, 1999, Bureau staff received from Consumer complaint #1999506372, contending that Aetna wrongfully denied benefits for type H insulin cartridges.
14. On November 2, 1999, Bureau staff, acting on behalf of the Superintendent, wrote to Aetna seeking its response to Consumer's enclosed complaint, and expressly requested the company to send a copy of its September 30, 1999 adverse utilization review notice. Aetna did not respond to the Bureau staff's inquiry, nor to a follow-up request sent by certified mail on November 22, 1999, which lack of responsiveness was the subject of a consent agreement with Aetna, Docket No. 99-39.
15. Once Aetna belatedly participated in the Bureau's investigation of Consumer's complaint, it wrote a letter to the Bureau dated January 18, 2000. In this letter, Aetna admitted its error in arguing the lack of coverage for Consumer's cartridges because there was no rider to the group plan. Aetna acknowledged the source of the error as its failure (extending for more than three years after the diabetes supplies mandate became effective) to update its pharmacy benefits database.
16. On November 10, 1999, Consumer appealed Aetna's September 30, 1999 decision refusing to authorize benefits for Consumer's insulin cartridges. The appeal enclosed and incorporated letters from Consumer, her father, her primary care provider and her endocrinologist, all urging that the cartridges are medically necessary to Consumer's treatment.
17. By letter of November 15, 1999, Aetna denied Consumer's first level appeal and informed Consumer she had 60 days to file a second level grievance. The letter identifies Aetna's first level utilization reviewer as R, "Regional Medical Director." R, whose medical title and reviewer qualifications are not stated, explains his reason for upholding the authorization denial as:

    The supply for pens [cartridges] does not meet criteria.

18. When a carrier denies a consumer's first level appeal, Rule 850(8)(G)(1)(c)(i)-(v) requires utilization review information the carrier must disclose in its adverse appeal determination notice, as follows:

    i) The names, titles and qualifying credentials of the person or persons evaluating the appeal;

    ii) A statement of the reviewers' understanding of the reason for the covered person's request for an appeal;

    iii) The reviewers' decision in clear terms and the clinical rationale in sufficient detail for the covered person to respond further to the health carrier's position;

    iv) A reference to the evidence or documentation used as the basis for the decision, including the clinical review criteria used to make the determination. The decision shall include instructions for requesting copies of any referenced evidence, documentation or clinical review criteria not previously provided to the covered person.…

v) A description of the process for submitting a request for second level grievance review pursuant to section 9(D), the procedures and time frames governing a second level grievance review, and the rights specified in section 9(D)(3)(c).

19. Aetna's adverse appeal determination notice of November 15, 1999 does not contain all information required by the five subsections set forth in the preceding paragraph. Absent are: (i) the qualifying credentials of R; (ii) a statement of R's understanding of Consumer's grounds for appeal; (iii) a clear statement of the reasons for R's determination, sufficiently meaningful to enable Consumer to prosecute a second level grievance; (iv) specific references to evidence and documents, including the clinical criteria on which R relied; and (v) instructions to Consumer for processing a second level grievance.
20. Rule 850(8)(G) states no limit on the time consumers may file either a first level appeal or a second level grievance.

CONCLUSIONS OF LAW

21. As set forth in paragraphs 3, 6, 7 and 8 above, in violation of 24-A M.R.S.A. § 4240 Aetna asserted that the policy does not pay for diabetes supplies, because there was no rider covering this benefit.
22. As set forth in paragraphs 3, 6, 7 and 8 above, Aetna did not honor the legislative mandate to cover diabetes supplies, in violation of 24-A M.R.S.A. § 4240.
23. As set forth in paragraphs 8 and 15 above, Aetna violated 24-A M.R.S.A. § 4240 by failing to diligently correct its Pharmacy Management database, resulting in denial of benefits for Consumer's diabetes supplies.
24. As set forth in paragraph 10 above, Aetna violated Rule 850(8)(E)(1) and (2) by failing to provide Consumer with written notice of its September 30, 1999 adverse utilization review determination refusing pre-authorization of benefits for insulin cartridges.
25. As set forth in paragraph 12 above, Aetna violated Rule 850(8)(E)(5) by failing to include in its September 30, 1999 adverse utilization review determination notice instructions for requesting Aetna's written clinical rationale.
26. As set forth in paragraph 12 above, Aetna violated Rule 850(8)(E)(5) by failing to include in its September 30, 1999 adverse utilization review determination notice a phone number to call for further appeal information or assistance.
27. As set forth in paragraphs 17 and 19 above, Aetna violated Rule 850(8)(G)(1)(c)(i) by failing to give notice in the November 15, 1999 adverse utilization review appeal determination of the qualifying peer credentials of the person who evaluated the appeal.
28. As set forth in paragraphs 17 and 19 above, Aetna violated Rule 850(8)(G)(1)(c)(ii) by failing to give notice in the November 15, 1999 adverse utilization review appeal determination of the reviewer's understanding of the grounds for the appeal.
29. As set forth in paragraphs 17 and 19 above, Aetna violated Rule 850(8)(G)(1)(c)(iii) by failing, in the November 15, 1999 adverse utilization review appeal determination, to state its decision in clear terms and to specify supporting clinical rationale in sufficient detail for Consumer to respond further to Aetna's position.

30. As set forth in paragraphs 17 and 19 above, Aetna violated Rule 850(8)(G)(1)(c)(iv) by failing to refer in the November 15, 1999 adverse utilization review appeal determination notice to the evidence, documents and clinical criteria on which Aetna relied for its decision, and by failing to provide instructions for Consumer to request this evidence and documentation.
31. As set forth in paragraphs 17 and 19 above, Aetna violated Rule 850(8)(G)(1)(c)(v) by not describing in the November 15, 1999 adverse utilization review appeal determination notice the process for Consumer to pursue a second level grievance.
32. As set forth in paragraphs 17 and 20 above, Aetna violated Rule 850(8)(G) by imposing in the November 15, 1999 adverse utilization review appeal determination notice an impermissible deadline for filing a second level grievance.

COVENANTS

33. A formal hearing in this complaint proceeding is waived and no appeal will be taken. This Consent Agreement is an enforceable agency action within the meaning of the Maine Administrative Procedure Act.
34. At the time of executing this Agreement, Aetna shall pay to the Maine Bureau of Insurance a penalty in the amount of $16,000, drawn to the Maine State Treasurer.
35. In consideration of Aetna's execution of and compliance with the terms of this Consent Agreement, the Superintendent agrees to forgo pursuing any disciplinary measure or other civil sanction for the violations described in paragraphs 3 through 20 above, other than those agreed to herein.

MISCELLANEOUS

36. Aetna understands and acknowledges that this Agreement will constitute a public record within the meaning of 1 M.R.S.A. § 402, will be available for public inspection and copying as provided by 1 M.R.S.A. § 408, and will be reported to the NAIC "RIRS" database.
37. The parties understand that nothing herein shall affect any right or interest of any person who is not a party to this Agreement.
38. This Agreement may be modified only by the written consent of the parties.
39. Aetna was informed of its right to consult with counsel of its own choice before executing this Agreement.
40. Nothing herein shall prohibit the Superintendent from seeking an order to enforce this Agreement, or from seeking additional sanctions in the event that Aetna does not comply with the above terms, or if the Superintendent receives evidence that further legal action is necessary for the protection of Maine consumers.

AETNA U.S.
HEALTHCARE, INC.

Dated:_____, 2001 By: _____

Signature

_____
Typed Name and Title

Subscribed and sworn to before me
this _____ day of _____, 2001.

_____
Notary Public

FOR THE MAINE
BUREAU OF INSURANCE

Dated: _____, 2001

_____
Alessandro A. Iuppa
Superintendent of Insurance

STATE OF MAINE
KENNEBEC ss

Subscribed and sworn to before me
this _____ day of _____, 2001

_____
Notary Public/Attorney at Law

FOR THE MAINE
ATTORNEY GENERAL

Dated: _____, 2001

_____
Carolyn Silsby
Assistant Attorney General

STATE OF MAINE
KENNEBEC ss

Subscribed and sworn to before me
this _____ day of _____, 2001

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Notary Public/Attorney at Law