SECTION 1. Chapter 27-18 of the General Laws entitled "Accident and Sickness Insurance Policies" is hereby amended by adding the following section:

27-18-79. Utilization of opioid medications with tamper-resistance formulations. -- (a) All individual or group health insurance plans or policies delivered, issued for delivery or review in this state on or after January 1, 2014, shall provide coverage for the utilization of opioid medications with tamper-resistance formulations in accordance with this section.

(b) "Tamper-resistant opioid formulation" means an opioid, that is prescribed to treat moderate to severe pain, addiction or other conditions, that incorporates tamper-resistant technology; approved by the United States Food and Drug Administration from an application that includes at least:

(1) One human tampering or abuse potential study; or

(2) A drug or a drug formulation that satisfies at least two (2) of the following qualities:

(i) Physical/chemical barriers that can prevent chewing, crushing, cutting, grating, or grinding designed to enhance euphoric effect.

(ii) Agonist/antagonist combinations that seek to interfere with, reduce, or defeat the euphoria associated with abuse.

(iii) Aversion that can produce an unpleasant effect if the dosage form is altered.

(iv) Delivery systems that offer resistance to abuse including, but not limited to, depot injections.
(v) Pro-drug techniques that limit opioid effect until digested in the gastrointestinal system.

(c) As used in this section, “prior authorization form” means a form developed by the department of health, with input from interested parties, designed for prescribers to document a patient's history or risk of abusing or diverting prescription medications.

(d) If, in the prescriber's reasonable professional judgment, tamper-resistant opioid formulation(s) are warranted in the treatment and support of a patient's recovery, a prior authorization form shall be available for submission to the plan/payer.

   (1) The form shall be available to prescribers electronically, by the department of health and by the health plan/payer.

   (2) The completed form or its data elements may be submitted electronically from the prescribing healthcare provider to the health plan/payer.

   (3) The department of health shall promulgate procedures that enable plans/payers to incorporate the contents of the prior authorization form into a plan's existing form for a specific medication.

   (4) The health plan/payer shall notify a healthcare provider of or make available to a healthcare provider a receipt of the request for prior authorization and any needed missing information within twenty-four (24) hours of receipt.

   (5) Prior authorization requests for tamper-resistant opioid formulations shall be administered by the plan/payers in the same fashion and time frames as are all other prior authorization requests accepted by the plan/payer.

   (e) Every plan/payer shall accept a prior authorization form from prescribers recommending tamper-resistant opioids for patients with a documented history of prescription drug abuse and/or diversion or a patient at high risk of relapsing into abuse of drugs.

   (f) It shall remain at the discretion of the plan/payer to approve or deny the prior authorization recommendation of the physician.

   (g) If the prior authorization is approved, it shall remain at the discretion of the plan/payer as to the appropriate tamper-resistant opioid to be therapeutically substituted.

   (h) Plan/payer denials remain subject to all existing patient utilization review due process rights.

   (i) The board of pharmacy shall promulgate and make available to prescribers a list of tamper-resistant opioid formulations, based on the study described in this section.

SECTION 2. Chapter 27-19 of the General Laws entitled “Nonprofit Hospital Service Corporations” is hereby amended by adding thereto the following section:
27-19-70. Utilization of opioid medications with tamper-resistance formulations. -- (a) All individual or group health insurance plans or policies delivered, issued for delivery or review in this state on or after January 1, 2014, shall provide coverage for the utilization of opioid medications with tamper-resistance formulations in accordance with this section.

(b) "Tamper-resistant opioid formulation" means an opioid, that is prescribed to treat moderate to severe pain, addiction or other conditions, that incorporates tamper-resistant technology; approved by the United States Food and Drug Administration from an application that includes at least:

(1) One human tampering or abuse potential study; or

(2) A drug or a drug formulation that satisfies at least two (2) of the following qualities:

(i) Physical/chemical barriers that can prevent chewing, crushing, cutting, grating, or grinding designed to enhance euphoric effect.

(ii) Agonist/antagonist combinations that seek to interfere with, reduce, or defeat the euphoria associated with abuse.

(iii) Aversion that can produce an unpleasant effect if the dosage form is altered.

(iv) Delivery systems that offer resistance to abuse including, but not limited to, depot injections.

(v) Pro-drug techniques that limit opioid effect until digested in the gastrointestinal system.

(c) As used in this section, "prior authorization form" means a form developed by the department of health, with input from interested parties, designed for prescribers to document a patient's history or risk of abusing or diverting prescription medications.

(d) If, in the prescriber's reasonable professional judgment, tamper-resistant opioid formulation(s) are warranted in the treatment and support of a patient's recovery, a prior authorization form shall be available for submission to the plan/payer.

(1) The form shall be available to prescribers electronically, by the department of health and by the health plan/payer.

(2) The completed form or its data elements may be submitted electronically from the prescribing healthcare provider to the health plan/payer.

(3) The department of health shall promulgate procedures that enable plans/payers to incorporate the contents of the prior authorization form into a plan's existing form for a specific medication.

(4) The health plan/payer shall notify a healthcare provider of or make available to a healthcare provider a receipt of the request for prior authorization and any needed missing
information within twenty-four (24) hours of receipt.

(5) Prior authorization requests for tamper-resistant opioid formulations shall be administered by the plan/payers in the same fashion and time frames as are all other prior authorization requests accepted by the plan/payer.

(e) Every plan/payer shall accept a prior authorization form from prescribers recommending tamper-resistant opioids for patients with a documented history of prescription drug abuse and/or diversion or a patient at high risk of relapsing into abuse of drugs.

(f) It shall remain at the discretion of the plan/payer to approve or deny the prior authorization recommendation of the physician.

g) If the prior authorization is approved, it shall remain at the discretion of the plan/payer as to the appropriate tamper-resistant opioid to be therapeutically substituted.

(h) Plan/payer denials remain subject to all existing patient utilization review due process rights.

(i) The board of pharmacy shall promulgate and make available to prescribers a list of tamper-resistant opioid formulations, based on the study described in this section.

SECTION 3. Chapter 27-20 of the General Laws entitled “Nonprofit Medical Service Corporations” is hereby amended by adding thereto the following section:

27-20-66. Utilization of opioid medications with tamper-resistance formulations. -- (a) All individual or group health insurance plans or policies delivered, issued for delivery or review in this state on or after January 1, 2014, shall provide coverage for the utilization of opioid medications with tamper-resistance formulations in accordance with this section.

(b) “Tamper-resistant opioid formulation” means an opioid, that is prescribed to treat moderate to severe pain, addiction or other conditions, that incorporates tamper-resistant technology; approved by the United States Food and Drug Administration from an application that includes at least:

(1) One human tampering or abuse potential study; or

(2) A drug or a drug formulation that satisfies at least two (2) of the following qualities:

(i) Physical/chemical barriers that can prevent chewing, crushing, cutting, grating, or grinding designed to enhance euphoric effect.

(ii) Agonist/antagonist combinations that seek to interfere with, reduce, or defeat the euphoria associated with abuse.

(iii) Aversion that can produce an unpleasant effect if the dosage form is altered.

(iv) Delivery systems that offer resistance to abuse including, but not limited to, depot injections.
(v) Pro-drug techniques that limit opioid effect until digested in the gastrointestinal system.

(c) As used in this section, “prior authorization form” means a form developed by the department of health, with input from interested parties, designed for prescribers to document a patient's history or risk of abusing or diverting prescription medications.

(d) If, in the prescriber's reasonable professional judgment, tamper-resistant opioid formulation(s) are warranted in the treatment and support of a patient's recovery, a prior authorization form shall be available for submission to the plan/payer.

(1) The form shall be available to prescribers electronically, by the department of health and by the health plan/payer.

(2) The completed form or its data elements may be submitted electronically from the prescribing healthcare provider to the health plan/payer.

(3) The department of health shall promulgate procedures that enable plans/payers to incorporate the contents of the prior authorization form into a plan's existing form for a specific medication.

(4) The health plan/payer shall notify a healthcare provider of or make available to a healthcare provider a receipt of the request for prior authorization and any needed missing information within twenty-four (24) hours of receipt.

(5) Prior authorization requests for tamper-resistant opioid formulations shall be administered by the plan/payers in the same fashion and time frames as are all other prior authorization requests accepted by the plan/payer.

(e) Every plan/payer shall accept a prior authorization form from prescribers recommending tamper-resistant opioids for patients with a documented history of prescription drug abuse and/or diversion or a patient at high risk of relapsing into abuse of drugs.

(f) It shall remain at the discretion of the plan/payer to approve or deny the prior authorization recommendation of the physician.

(g) If the prior authorization is approved, it shall remain at the discretion of the plan/payer as to the appropriate tamper-resistant opioid to be therapeutically substituted.

(h) Plan/payer denials remain subject to all existing patient utilization review due process rights.

(i) The board of pharmacy shall promulgate and make available to prescribers a list of tamper-resistant opioid formulations, based on the study described in this section.

SECTION 4. Chapter 27-41 of the General Laws entitled “Health Maintenance Organizations” is hereby amended by adding thereto the following section:
27-41-83. Utilization of opioid medications with tamper-resistance formulations. -- (a) All individual or group health insurance plans or policies delivered, issued for delivery or review in this state on or after January 1, 2014, shall provide coverage for the utilization of opioid medications with tamper-resistance formulations in accordance with this section.

(b) "Tamper-resistant opioid formulation" means an opioid, that is prescribed to treat moderate to severe pain, addiction or other conditions, that incorporates tamper-resistant technology; approved by the United States Food and Drug Administration from an application that includes at least:

(1) One human tampering or abuse potential study; or
(2) A drug or a drug formulation that satisfies at least two (2) of the following qualities:
   (i) Physical/chemical barriers that can prevent chewing, crushing, cutting, grating, or grinding designed to enhance euphoric effect.
   (ii) Agonist/antagonist combinations that seek to interfere with, reduce, or defeat the euphoria associated with abuse.
   (iii) Aversion that can produce an unpleasant effect if the dosage form is altered.
   (iv) Delivery systems that offer resistance to abuse including, but not limited to, depot injections.
   (v) Pro-drug techniques that limit opioid effect until digested in the gastrointestinal system.

(c) As used in this section, "prior authorization form" means a form developed by the department of health, with input from interested parties, designed for prescribers to document a patient's history or risk of abusing or diverting prescription medications.

(d) If, in the prescriber's reasonable professional judgment, tamper-resistant opioid formulation(s) are warranted in the treatment and support of a patient's recovery, a prior authorization form shall be available for submission to the plan/payer.

(1) The form shall be available to prescribers electronically, by the department of health and by the health plan/payer.
(2) The completed form or its data elements may be submitted electronically from the prescribing healthcare provider to the health plan/payer.
(3) The department of health shall promulgate procedures that enable plans/payers to incorporate the contents of the prior authorization form into a plan's existing form for a specific medication.
(4) The health plan/payer shall notify a healthcare provider of or make available to a healthcare provider a receipt of the request for prior authorization and any needed missing
information within twenty-four (24) hours of receipt.

(5) Prior authorization requests for tamper-resistant opioid formulations shall be administered by the plan/payers in the same fashion and time frames as are all other prior authorization requests accepted by the plan/payer.

(e) Every plan/payer shall accept a prior authorization form from prescribers recommending tamper-resistant opioids for patients with a documented history of prescription drug abuse and/or diversion or a patient at high risk of relapsing into abuse of drugs.

(f) It shall remain at the discretion of the plan/payer to approve or deny the prior authorization recommendation of the physician.

(g) If the prior authorization is approved, it shall remain at the discretion of the plan/payer as to the appropriate tamper-resistant opioid to be therapeutically substituted.

(h) Plan/payer denials remain subject to all existing patient utilization review due process rights.

(i) The board of pharmacy shall promulgate and make available to prescribers a list of tamper-resistant opioid formulations, based on the study described in this section.

SECTION 5. This act shall take effect on October 1, 2013.

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EXPLANATION
BY THE LEGISLATIVE COUNCIL
OF
A N   A C T
RELATING TO INSURANCE -- HEALTH INSURANCE

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1 This act would give the prescribers of medication the discretion to request a prior
2 authorization for a tamper-resistant opioid medication for patients with a history of
3 abuse/diversion or at risk of abusing drugs.
4 This act would take effect on October 1, 2013.

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