N O R T H C A R O L I N A G E N E R A L A S S E M B L Y

HOUSE SELECT COMMITTEE ON STEP THERAPY

REPORT TO THE
2016 SESSION
of the
2015 GENERAL ASSEMBLY
OF NORTH CAROLINA

APRIL 19, 2016

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TRANSMITTAL LETTER

April 19, 2016

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TO THE MEMBERS OF THE 2016 REGULAR SESSION
OF THE 2015 GENERAL ASSEMBLY

The HOUSE SELECT COMMITTEE ON STEP THERAPY, respectfully submits the following report to the 2016 Regular Session of the 2015 General Assembly.

David R. Lewis

Rep. David R. Lewis (Chair)

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COMMITTEE PROCEEDINGS

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The House Select Committee on Step Therapy met 4 times after the 2015 Regular Session. The following is a brief summary of the Committee's proceedings. Detailed minutes and information from each Committee meeting are available in the Legislative Library. Committee meeting handouts and speaker testimonials are available on the Committee website here.

Overview of Topics and Presenters

December 14, 2015
Step Therapy

- Patrick Stone, State Government Relations Manager for the National Psoriasis Foundation
- Lu-Ann Perryman, Representative for Americas Health Insurance Plans
- P.J. Leary, psoriasis patient and patient advocate
- Donna Kaufman, National Patient Advocate Foundation
- Michelle McArthur, rheumatoid arthritis patient and patient advocate
- Logan Govan, 12 year old polyarticular juvenile arthritis patient and patient advocate
- Mindy Govan, mother and patient advocate
- Ben Twilley, Senior Manager of State Government Affairs for Express Scripts

Representative Lewis presided over the meeting. In addition to the above scheduled speakers, Gregg Thompson from the National Federation of Independent Business was present in the galley and made a statement. The meeting ended following a question and answer session between the members and the speakers.

February 24, 2016
Step Therapy

- Amy Prentice, State Government Relations Manager for the National Psoriasis Foundation
- Dr. John C. Murray, Professor of Dermatology at Duke University Medical Center
- Dr. Gregory Schimizzi, Carolina Arthritis Associates and on behalf of the North Carolina Rheumatology Association and the Coalition of State Rheumatology Organizations
- Dr. John R. Scagnelli, Raleigh Neurology Associates and on behalf of the National Multiple Sclerosis Society, the North Carolina Neurologic Society, and the Alliance for Patient Access
- Dr. Gwenesta B. Melton, Lafayette Clinic

- Thomas Friedman, Representative of North Carolina Department of Treasurer and State Health Plan

Representative Lewis presided over the meeting. The meeting ended following a question and answer session between the members and the speakers.

March 23, 2016

Abuse-Deterrent Opioids

- Fred Brason, Executive Director of Project Lazarus
- Dr. Bob Wilson, Pain Society of the Carolinas
- Captain Eric Smith, Wilson Police Department
- Mike Cannon, parent of overdose victim and advocate for abuse-deterrent opioids
- Estay Green, Director of Pharmacy Programs at Blue Cross Blue Shield
- Thomas Friedman, Representative of North Carolina Department of Treasurer and State Health Plan

Representatives Lewis and Dobson presided over the meeting. In addition to the above speakers, Committee Clerk Mark Coggins read a letter from Judy S. Billings, Special Agent in Charge at the North Carolina State Bureau of Investigation. Members asked the individual speakers questions throughout the meeting.

April 19, 2016

Committee Consideration of Its Legislative Recommendations and Report to the 2016 Session of the 2015 General Assembly

Representative Dobson presided over the meeting. The Committee heard from two speakers: Amber Proctor, PharmD, Clinical Oncology Specialist at UNC hospital and Clinical Assistant Professor at UNC's Eschelman School of Pharmacy and Diane Kerkhoff, a cancer patient and patient advocate. Public comments were made by Chris Evans from Blue Cross Blue Shield of North Carolina and Ben Twilley from Express Scripts.

Following the speakers' presentations and public comments, Committee Counsel presented the Committee's draft report to the 2016 Session of the 2015 General Assembly. The report was adopted and Committee staff was authorized to revise the report to reflect the proceedings of the meeting and to address technical corrections to the report.

FINDINGS AND RECOMMENDATIONS

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Findings – Step Therapy

The House Select Committee on Step Therapy has considered the speakers' presentations and materials presented on step therapy and the information obtained during question and answer sessions and discussions at the committee meetings and finds the following:

- Step therapy affects patients suffering from a wide-range of chronic and life-threating diseases and medical conditions including multiple sclerosis, psoriasis, and rheumatoid arthritis.
- Step therapy can cause setbacks in a patient's treatment resulting in time missed from work and additional medical treatment including hospitalization.
- Step therapy protocols can vary depending on the health benefit plan and the pharmacy benefit manager (PBM).
    - There is a lack of consistency among plans in the number of steps a patient may be required to follow before coverage will be provided for the drug first selected by the patient's doctor to treat his or her condition. Some plans or PBMs may require two (2) steps and others may require a patient to try up to 4 (four) prescription medications before coverage will be provided.
    - When and how a patient or doctor can request an exemption from or override of a step therapy protocol depends on the factors considered under that plan's protocol. Factors may include if the patient has unsuccessfully tried the step therapy medication under another plan, the patient is stable on his or her current medication, and the step therapy medication is ineffective, contraindicated, or may be physically harmful to the patient and not in his or her best interest.
    - Who is responsible for drafting and enforcing the protocol may also depend on the practices and procedures of the insurance carrier or PBM. For example, some protocols may be developed, reviewed, and enforced by an independent, external review committee while others may be managed by an in-house committee.
- Step therapy protocols affect both younger and older patients.
- Step therapy protocols increase the administrative burdens and costs of medical providers and their staff.
- There are differing opinions as to whether step therapy protocols have their intended effect of reducing and containing prescription drug and health care costs.

Recommendation #1 – Amend Step Therapy Protocols

Based on the above findings, the House Select Committee on Step Therapy recommends that step therapy protocols be amended to ensure proper administration of

step therapy including requiring that step therapy protocols be based on clinical practice guidelines that are developed and endorsed by an independent, multi-disciplinary panel and that both patients and practitioners have access to a clear, convenient and transparent process to request an override determination which will be granted under certain circumstances. Therefore, the Committee recommends that during the 2016 Session, the General Assembly enact legislation [2015-MRz-16], to assist patients and practitioners in obtaining their preferred medications.

Findings – Abuse-deterrent Opioid Analgesics

The House Select Committee on Step Therapy has considered the speakers' presentations and materials presented specifically relating to step therapy and abuse-deterrent opioid analgesics and the information obtained during question and answer sessions and discussions at the committee meetings and finds the following:

- Opioid abuse in North Carolina is a serious and severe problem and measures must be taken to deter abuse.
  - Testimony indicated that the number of drug overdose deaths doubled between 1999 and 2013.
  - Opioid overdose led to the death of 1,358 North Carolinians in 2014. This is an increase of 7% since 2013.
  - A 2013 National Survey on Drug Use and Health conducted by Center for Behavioral Health Statistics and Quality, Substance Abuse and Mental Health Services Administration, U.S. Department of Health and Human Services, and by RTI International found that over 63% of all people who abuse prescriptions drugs obtained the drugs from family and friends. Of these diverted drugs, the vast majority were *originally* obtained legally through a medical provider.
- Access to abuse-deterrent opioid analgesics should be increased.
  - Abuse-deterrent opioid analgesics are currently in existence; there are six opioids that have abuse-deterrent characteristics and many more in development.
  - The North Carolina State Bureau of Investigation credits tamper-resistant features of the reformulation of OxyContin with the dramatic decrease in the diversion of this drug of the past years in North Carolina.
  - The United States Food and Drug Administration has labelled abuse-deterrent opioids analgesics as a priority.

Recommendation #2 – Increase Access to Abuse-deterrent Opioid Analgesics

Based on the above findings, the House Select Committee on Step Therapy recommends removing barriers to patient access to abuse-deterrent opioids. This includes the barrier of step therapy - requiring the use of an opioid analgesic without abuse-deterrent properties before authorizing the use of an abuse-deterrent opioid analgesic. Therefore, the Committee recommends that during the 2016 Session the General Assembly enact legislation [2015-MRz-16], an important step in creating greater access to these life-saving drugs.

Appendix A

COMMITTEE MEMBERSHIP

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2015-2016

Speaker of the House of Representatives Appointments:

Rep. David R. Lewis (Chair)

Rep. Josh Dobson (Vice-Chair)
Rep. Dean Arp
Rep. William D. Brisson
Rep. Ted Davis, Jr.
Rep. Nelson Dollar
Rep. Rosa U. Gill
Rep. Yvonne Lewis Holley
Rep. D. Craig Horn
Rep. Darren G. Jackson
Rep. Pat McElraft
Rep. Gregory F. Murphy, MD
Rep. John Szoka
Rep. Michael H. Wray
Rep. Lee Zachary

Committee Staff:

Tim Hovis, Committee Counsel, Legislative Analysis Division
Amy Jo Johnson, Committee Counsel, Legislative Drafting Division
Kristen Harris, Committee Counsel, Legislation Analysis Division
David Vanderweide, Committee Staff, Fiscal Research Division

Committee Clerk:

Mark Coggins, Office of Representative David Lewis

Appendix B

COMMITTEE CHARGE/STATUTORY AUTHORITY

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HOUSE SELECT COMMITTEE ON STEP THERAPY
TO THE HONORABLE MEMBERS OF THE
NORTH CAROLINA HOUSE OF REPRESENTATIVES

Section 1. The House Select Committee on Step Therapy (hereinafter "Committee") is established by the Speaker of the House of Representatives pursuant to G.S. 120-19.6(a1) and Rule 26(a) of the Rules of the House of Representatives of the 2015 General Assembly.

Section 2. The Committee consists of fifteen members appointed by the Speaker of the House of Representatives. The membership of the Committee shall include legislators as specified below. Members serve at the pleasure of the Speaker of the House of Representatives. The Speaker of the House of Representatives may dissolve the Committee at any time. Vacancies are filled by the Speaker of the House of Representatives. A Chair, Vice Chair, or other member of the Committee continues to serve until a successor is appointed.

Representative David Lewis, Chair	Representative Craig Horn
Representative Josh Dobson, Vice Chair	Representative Darren Jackson
Representative Dean Arp	Representative Pat McElraft
Representative William Brisson	Representative Gregory Murphy, MD
Representative Ted Davis, Jr.	Representative John Szoka
Representative Nelson Dollar	Representative Michael Wray
Representative Rosa Gill	Representative Lee Zachary
Representative Yvonne Lewis Holley	

Section 3. The Committee is tasked with studying the prescription benefit management tool known as "step therapy" to assess the impact on patients' access to care. The Committee shall analyze the costs and benefits of the utilization of "step therapy," including any potential negative consequences for patients and providers. The Committee shall also assess the impact "step therapy" has on access to abuse-deterrent opioid analgesics.

Section 4. The Committee shall meet upon the call of the Chair. A quorum of the Committee shall be a majority of its members. No action may be taken except by majority vote at a meeting at which a quorum is present.

Section 5. The Committee, while in the discharge of its official duties, may exercise all powers provided for under G.S. 120-19 and Article 5A of Chapter 120 of the General Statutes. The Committee may contract for professional, clerical, or consultant services, as provided by G.S. 120-32.02.

Section 6. Members of the Committee shall receive per diem, subsistence, and travel allowance as provided in G.S. 120-3.1

Section 7. The expenses of the Committee including per diem, subsistence, travel allowances for Committee members, and contracts for professional or consultant services shall be paid upon the written approval of the Speaker of the House of Representatives pursuant to G.S. 120-32.02(c) and G.S. 120-35 from funds available to the House of Representatives for its operations. Individual expenses of $5,000 or less, including per diem, travel and subsistence expenses of members of the Committee, and clerical expenses shall be paid upon the authorization of the Chair of the Committee. Individual expenses in excess of $5,000 shall be paid upon the written approval of the Speaker of the House of Representatives.

Section 8. The Legislative Services officer shall assign professional and clerical staff to assist the Committee in its work. The Director of Legislative Assistants of the House of Representatives shall assign clerical support staff to the Committee.

Section 9. The Committee may meet at various locations around the State in order to promote greater public participation in its deliberations.

Section 10. The Committee may submit an interim report on the results of its findings, including any proposed legislation, to the members of the House of Representatives at any time. The Committee may submit a final report on the results of its findings, including any proposed legislation to the members of the House of Representatives prior to the convening of the Short Session of the 2015 General Assembly. Reports shall be submitted by filing a copy of the report with the Office of the Speaker of the House of Representatives, the House principal Clerk, and the Legislative Library. The Committee terminates upon the convening of the Short Session of the 2015 General Assembly or upon the filing of its final report, whichever occurs first.

Effective this the 8th day of December 2015.

Tim Moore
Speaker

Appendix C

LEGISLATIVE PROPOSALS

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GENERAL ASSEMBLY OF NORTH CAROLINA
SESSION 2015

H **D**

BILL DRAFT 2015-MRz-16 [v.7] (03/31)

(THIS IS A DRAFT AND IS NOT READY FOR INTRODUCTION)
04/15/2016 01:22:24 PM

Short Title: Reduce Barriers to Improve NC Health & Safety. (Public)

Sponsors:

Referred to:

A BILL TO BE ENTITLED

AN ACT TO INCREASE ACCESS TO ABUSE-DETERRENT OPIOID ANALGESICS AND TO ENSURE THE PROPER ADMINISTRATION OF STEP THERAPY PROTOCOLS FOR PRESCRIPTION DRUGS, AS RECOMMENDED BY THE HOUSE SELECT COMMITTEE ON STEP THERAPY.

Whereas, opioid-related deaths have doubled in North Carolina between 1999 and 2013; and

Whereas, a 2013 National Survey on Drug Use and Health found that over 63% of all people who abuse prescriptions drugs obtained the drugs from family and friends; and

Whereas, opioid abuse in North Carolina is a serious and severe problem that affects the health, social, and economic welfare of this State; and

Whereas, abuse-deterrent opioid analgesics have been labelled a top priority by the United States Food and Drug Administration; and

Whereas, patient access to abuse-deterrent opioid analgesics is an important step in addressing the opioid abuse epidemic; and

Whereas, health benefit plans are increasingly making use of step therapy protocols under which patients are required to try one or more prescription drugs before coverage is provided for a drug selected by the patient's health care provider; and

Whereas, when step therapy protocols are based on well-developed scientific standards and administered in a flexible manner that takes into account the individual needs of patients, the protocols can play an important role in controlling health care costs; and

Whereas, in some cases, requiring a patient to follow a step therapy protocol may have adverse and even dangerous consequences for the patient who may either not realize a benefit from taking a prescription drug or may suffer harm from taking an inappropriate drug; and

Whereas, without uniform policies in the State for step therapy protocols, patients may not receive the best and most appropriate treatment; and

Whereas, it is imperative that step therapy protocols preserve the health care provider's right to make treatment decisions in the best interest of the patient; and

Whereas, the General Assembly declares it a matter of public interest that it require health benefit plans base step therapy protocols on appropriate clinical practice guidelines developed by independent experts with knowledge of the condition or conditions under consideration; that patients be exempt from step therapy protocols when inappropriate or otherwise not in the best interest of the patients; and that patients have access to a fair, transparent, and independent process for requesting an exception to a step therapy protocol when appropriate; Now, therefore,

The General Assembly of North Carolina enacts:

SECTION 1. Article 3 of Chapter 58 of the General Statutes is amended by adding a new section to read:

"**§ 58-3-295. Coverage for abuse-deterrent opioid analgesics.**

(a) The following definitions apply to this section:

(1) Abuse-deterrent opioid analgesic drug product. – A brand or generic opioid analgesic drug product approved by the United States Food and Drug Administration with an abuse-deterrence labeling claim that indicates that the drug product is expected to deter abuse.

(2) Health benefit plan. – As defined in G.S. 58-3-167.

(3) Opioid analgesic drug product. – A drug product in the opioid analgesic drug class prescribed to treat moderate to severe pain or other conditions in immediate-release, extended-release, or long-acting form, regardless of whether or not combined with other drug substances to form a single drug product or dosage form.

(b) Any health benefit plan that provides coverage for abuse-deterrent opioid analgesic drug products may impose a prior authorization requirement for an abuse-deterrent opioid analgesic drug product only if the health benefit plan imposes the same prior authorization requirement for each opioid analgesic drug product without an abuse-deterrence labeling claim.

(c) No health benefit plan that provides coverage for abuse-deterrent opioid analgesic drug products may require the use of an opioid analgesic drug product without an abuse deterrence labeling claim before authorizing the use of an abuse-deterrent opioid analgesic drug product."

SECTION 2. Article 50 of Chapter 58 of the General Statutes is amended by adding a new Part to read:

"Part 8. Administration of Step Therapy Protocols.

"**§ 58-50-301. Definitions.**

As used in this Article, unless the context clearly requires otherwise:

(1) Clinical practice guidelines. – A systematically developed statement to assist health care provider and patient decisions about appropriate health care for specific clinical circumstances and conditions.

(2) Clinical review criteria. – The written screening procedures, decision abstracts, clinical protocols, and practice guidelines used by an insurer, health plan, or utilization review organization to determine the medical necessity and appropriateness of health care services.

(3) Step therapy override determination. – A determination as to whether a step therapy protocol should apply in a particular situation or whether the step therapy protocol should be overridden in favor of immediate

coverage of the health care provider's selected prescription drug. This determination is based on a review of the patient's or prescriber's request for an override along with supporting rationale and documentation.

(4) Step therapy protocol. – A protocol or program that establishes the specific sequence in which prescription drugs for a specified medical condition are medically appropriate for a particular patient and are covered by an insurer or health plan.

(5) Utilization review organization. – As defined in G.S. 59-50-61(a)(18).

"**§ 58-50-305. Clinical review criteria.**

Clinical review criteria used to establish a step therapy protocol shall be based on clinical practice guidelines that meet all the following requirements:

(1) Recommend that the prescription drugs be taken in the specific sequence required by the step therapy protocol.

(2) Are developed and endorsed by an independent, multidisciplinary panel of experts not affiliated with a health benefit plan or utilization review organization.

(3) Are based on high-quality studies, research, and medical practice.

(4) Are created by an explicit and transparent process that includes all of the following:

a. Minimizes biases and conflicts of interest.

b. Explains the relationship between treatment options and outcomes.

c. Rates the quality of the evidence supporting recommendations.

d. Considers relevant patient subgroups and preferences.

(5) Are continually updated through a review of new evidence and research.

"**§ 58-50-310. Exceptions process transparency.**

(a) Exceptions Process. – When coverage of a prescription drug for the treatment of any medical condition is restricted for use by a health benefit plan or utilization review organization through the use of a step therapy protocol, the patient and prescribing practitioner shall have access to a clear and convenient process to request a step therapy override determination. A health benefit plan or utilization review organization may use its existing medical exceptions process to satisfy this requirement. The process shall be made easily accessible on the health benefit plan's or utilization review organization's Web site.

(b) Exceptions. – A step therapy override determination request shall be expeditiously granted if any of the following apply:

(1) The required prescription drug is contraindicated or will likely cause an adverse reaction or physical or mental harm to the patient.

(2) The required prescription drug is expected to be ineffective based on the known relevant physical or mental characteristics of the patient and the known characteristics of the prescription drug regimen.

(3) The patient has tried the required prescription drug while under their current or a previous health insurance or health benefit plan or another prescription drug in the same pharmacologic class or with the same

mechanism of action and such prescription drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event.

(4) The required prescription drug is not in the best interest of the patient, based on medical appropriateness.

(5) The patient is stable on a prescription drug selected by their health care provider for the medical condition under consideration.

(c) Effect of Exception. – Upon the granting of a step therapy override determination, the health benefit plan or utilization review organization shall authorize coverage for the prescription drug prescribed by the patient's treating health care provider, provided such prescription drug is a covered prescription drug under such policy or contract.

(d) Limitations. – This section shall not be construed to prevent any of the following:

(1) A health benefit plan or utilization review organization from requiring a patient to try an AB-rated generic equivalent prior to providing coverage for the equivalent branded prescription drug.

(2) A health care provider from prescribing a prescription drug that is determined to be medically appropriate.

"**§ 58-50-315. Rules and limitation of Part.**

(a) The Commissioner shall adopt rules to implement this Article.

(b) Nothing in this Part shall be construed to impact an insurers' ability to substitute a generic drug for a name brand drug."

SECTION 3. This act becomes effective October 1, 2016, and applies to insurance contracts issued, renewed, or amended on or after that date.