

1275 Pennsylvania Avenue, NW Suite 700 Washington, DC 20004

December 8, 2016

Ms. Jennifer Patterson Health Policy Legal Counsel New Hampshire Insurance Department 21 S. Fruit St., Suite 14 Concord, NH 03301

## *Re: Uniform Prescription Drug Prior Authorization Form Regulations - Preliminary Draft* 9.21.2016

Dear Ms. Patterson:

CVS Health, on behalf of its subsidiaries and affiliated entities, appreciates the opportunity to comment on the draft regulations and standardized prior authorization form. As mentioned throughout the stakeholder process, CVS Health continues to have serious concerns with the current draft regulations and the impact they will ultimately have on patients.

CVS Health is a pharmacy innovation company helping people on their path to better health. It is the largest pharmacy health care provider in the United States. Through its more than 9,600 retail drugstores, more than 1,100 walk-in medical clinics, a leading pharmacy benefits manager (PBM) with more than 70 million plan members, a dedicated senior pharmacy care business serving more than one million patients per year, and expanding specialty pharmacy services, CVS Health enables people, businesses and communities to manage health in more affordable, effective ways. This unique integrated model increases access to quality care, delivers better health outcomes, and lowers overall health care costs.

As a pharmacy benefit manager (PBM), CVS/Caremark utilizes a number of tools to manage its clients' (health plans and employers) formularies – including prior authorization. Prior authorization ensures the safety and efficacy of treatment. Below are our concerns with how the draft regulations would restrict our ability to properly care for patients.

## Ins. 2705.04 <u>Use of Uniform Prior Authorization Forms and Electronic Standard for Prescription</u> <u>Drug Benefits</u>

While we understand that the authorizing legislation provides for the creation and use of a uniform prior authorization form, the regulations as currently drafted do not take into account that some flexibility is needed to collect all of the information necessary to make a timely and appropriate determination. The current pharmaceutical market contains many complex drugs that are precisely targeted to very specific patient populations. These patients may share a common diagnosis, but their drug therapy must be further guided by genomics, lab values, organ functionality, and other patient-specific factors to confirm that the right patient is prescribed the right drug at the right time. For example, for patients with growth hormone deficiency, the selection of the right growth hormone product is guided not only by the diagnosis but also by very precise patient characteristics. The



information needed to verify the safety of the patient's prescription varies drastically by the age of the patient down to the *month*—different information is needed depending on whether the patient is less than four months old, older than 24 months, or an adult. Only with this information can it be assured that clinical best practices and safety guidelines are followed, and the proposed rule and proposed prior authorization form would not permit important additional requests for information in these cases.

We respectfully ask that you consider language that would allow flexibility in the form so that we may request additional critical information that may be necessary to ensure proper utilization and patient safety.

## Ins. 2705.06 Standards for Electronic Prior Authorization Processes

House Bill 1608, the authorizing legislation for these regulations, states that rules developed by the Department, "shall support adoption of nationally recognized standards for electronic prior authorization of prescription drugs, including those provided by the National Council for Prescription Drug Programs [NCPDP] or an equivalent organization as available." The draft rules, however, create a framework that is inconsistent with the NCPDP guidelines and would prevent the effective use of electronic prior authorization. It is inconsistent with current operating practice to require that the electronic prior authorization standards mirror the uniform form. It is an apples to oranges comparison because they are different platforms and don't operate in the same way.

Furthermore, the authorizing legislation <u>does not</u> actually require that the electronic prior authorization process mirror the requirements developed for the uniform form. We believe that by doing so, the Department would be undermining the intent of the legislation which was to allow flexibility and speed in the electronic prior authorization process as an alternative to the uniform form. Instead, the current draft regulations would create additional time-delaying hurdles for the dispensing of medication to patients.

We respectfully request that the Department draft regulations that adhere to the NCPDP standards for electronic prior authorization, and not place additional burdensome restrictions that would only serve to delay a patient's access to medications.

Thank you for your consideration of our concerns, and we look forward to continuing to work with you. If you have any questions, please do not hesitate to contact me at (202) 772-3501.

Sincerely,

Melessa A Schulman

Melissa Schulman Senior Vice President, Government and Public Affairs CVS Health