PCMA

January 21, 2016

Nick Gerhart
Commissioner, Insurance Division
Two Ruan Center
601 Locust Street, 4th Floor
Des Moines IA 50309-3738

Re: Request for Delay of Effective Date of Prior Authorization—Prescription Drug Benefits Regulation

Dear Commissioner Gerhart:

On behalf of the Pharmaceutical Care Management Association (PCMA), I write to respectfully request a 70-day delay of the effective date of the Prior Authorization—Prescription Drug Benefits Regulation expected to go into effect in early February. PCMA is the national trade association representing America's pharmacy benefit managers (PBMs), which administer prescription drug plans for more than 246 million Americans with health coverage provided through Fortune 500 employers, health insurance plans, labor unions, Medicaid managed care, and Medicare Part D.

We first would like to reiterate that we share your goal to ensure that prior authorization processes are clear and understandable for providers, and that patients get the proper medications in an expeditious manner. PCMA and member companies also thank you for listening to our concerns regarding encouraging the use of advances in technology (e-Prior Auth) and for acknowledging that there is not a one-size-fits-all duration of medication approvals and that clinical appropriateness should govern.

PCMA and member companies remain concerned, however, about the effective date of the regulation. Though the concept of the prior authorization rule has been at issue for over a year, the regulation has yet to be finalized, and as we understand it, will be effective February 10, 2016. As you recall, this regulation has gone through many changes over time. The original proposed regulation was released in 2014 and withdrawn in early 2015 after the regulation went through the Legislative Administrative Rules Review Committee. Later in 2015, the final statute was enacted, upon which these regulations have been drafted. Given the fact that the Legislative Administrative Rules Review Committee still has an opportunity to suspend or delay the regulation at its meeting the first week of February, February 5, 2016 is the *earliest* possible date for there to be certainty on the language and effectiveness of this regulation.

It is our understanding that the regulation's terms will become effective on February 10, 2016 unless the Administrative Rules Review Committee delays the effective date. Without a delay, companies would have 5 days—only 3 business days—to come into compliance. Although member companies have been preparing for the implementation of *a* regulation on prior authorization, it has, up to this point, been unclear exactly what those terms will be. Regulated businesses need certainty on language before they can adjust processes and fully implement regulatory changes.

Our specific concerns about the brief time in which PBMs must implement the terms of this rule are related to the time it takes to review the final regulation, determine which of our clients and products are impacted by the regulation, make the necessary adjustments to policies that are

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associated with those clients and products, and program the necessary changes into the proper IT systems so those changes are fully implemented, all of which cannot be fully put into place until the regulation is finalized (at the earliest, February 5, 2016).

Regarding the posting of the clinical criteria for medication approvals, ensuring that the PBM is in compliance requires an identification and analysis of which client companies and product lines are affected by the regulation, understanding the clinical criteria under which medications are authorized for those particular clients and products, and configuring the IT systems to ensure that this clinical criteria information is available online. A similar process must take place for implementing changes to the health plan appeals process. Companies must identify their clients to which this regulation applies and make necessary adjustments in the appeals processes for those clients to ensure that they are in line with the finalized regulation.

In addition, changes to the prior authorization decision "turn-around time" (TAT) must be made differently for different clients. This requires identification and analysis of the clients that the regulation impacts and updating the TAT deadlines for those clients. Also, PBMs may need to adjust the prior authorization determination form letters depending on the needs of the client.

Finally, the single prior authorization form must still be submitted to the Division for review and approval before posting online. Even if the form is ready to be sent by PBMs on February 5 when the Administrative Rules Review Committee meets and determines whether this regulation is approved, Division staff must take the time to review and approve the forms before the PBMs can post the forms. Each step in this process will take time as well, and it will likely be impossible for the Division and PBMs to complete all of these steps by February 10.

Further exacerbating all of this is that due to the nature of annual contract cycles, the beginning of the year is the busiest time for implementation of IT changes, and there is a backlog of work that takes several weeks to get through. We feel that adding this layer of adjustments that must be made in response to regulatory language made final only a few days before the compliance deadline is troublesome.

PCMA would like to reiterate its commitment to ensuring clear and efficient prior authorization process requirements that enable medication therapies to reach patients in a safe and expeditious manner. We respectfully request that you amend your rule to provide for a 70-day extension of the effective date, so changes made in compliance with this regulation can seamless for providers and patients.

Thank you again for the opportunity to comment on this regulation. If you have any questions, please do not hesitate to contact me at 202-756-5743.

Sincerely,

April C. Alexander

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Senior Director, State Affairs

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