The following information is being provided pursuant to the requirements of Executive Order 2011-01K and Senate Bill 2 of the 129th General Assembly, which require state agencies, including the State of Ohio Board of Pharmacy, to draft rules in collaboration with stakeholders, assess and justify an adverse impact on the business community (as defined by S.B. 2), and provide an opportunity for the affected public to provide input on the following rules.

New:

- 4729-5-30.02 – The rule outlines the prescription requirements for prescribing chloroquine or hydroxychloroquine. The rule does not apply to inpatient prescriptions.

Comments on the proposed rules will be accepted until close of business on April 28, 2020. Please send all comments to the following email address: RuleComments@pharmacy.ohio.gov

In addition, please copy your comments to: CSIPublicComments@governor.ohio.gov
Business Impact Analysis

| Agency, Board, or Commission Name: | State of Ohio Board of Pharmacy |
| Rule Contact Name and Contact Information: | Cameron McNamee Cameron.mcnamee@pharmacy.ohio.gov |
| Regulation/Package Title (a general description of the rules’ substantive content): | Prescription requirements for chloroquine or hydroxychloroquine |
| Rule Number(s): | 4729:1-2-09, 4729:1-2-10, 4729:2-2-11, 4729:3-2-06 |
| Date of Submission for CSI Review: | 4/17/20 |
| Public Comment Period End Date: | 4/28/20 |

| Rule Type/Number of Rules: |
| New/ | 1 | rules |
| Amended/ | ___ | rules (FYR? ___) |
| No Change/ | ___ | rules (FYR? ___) |
| Rescinded/ | ___ | rules (FYR? ___) |

The Common Sense Initiative is established in R.C. 107.61 to eliminate excessive and duplicative rules and regulations that stand in the way of job creation. Under the Common Sense Initiative, agencies must balance the critical objectives of regulations that have an adverse impact on business with the costs of compliance by the regulated parties. Agencies should promote transparency, responsiveness,
predictability, and flexibility while developing regulations that are fair and easy to follow. Agencies should prioritize compliance over punishment, and to that end, should utilize plain language in the development of regulations.

**Reason for Submission**

1. R.C. 106.03 and 106.031 require agencies, when reviewing a rule, to determine whether the rule has an adverse impact on businesses as defined by R.C. 107.52. If the agency determines that it does, it must complete a business impact analysis and submit the rule for CSI review.

Which adverse impact(s) to businesses has the agency determined the rule(s) create?

The rule(s):

- ☐ Requires a license, permit, or any other prior authorization to engage in or operate a line of business.

- ☒ Imposes a criminal penalty, a civil penalty, or another sanction, or creates a cause of action for failure to comply with its terms.

- ☐ Requires specific expenditures or the report of information as a condition of compliance.

- ☐ Is likely to directly reduce the revenue or increase the expenses of the lines of business to which it will apply or applies.

**Regulatory Intent**

2. Please briefly describe the draft regulation in plain language. Please include the key provisions of the regulation as well as any proposed amendments.

**New:**

- 4729-5-30.02 – The rule outlines the prescription requirements for prescribing chloroquine or hydroxychloroquine. The rule does not apply to inpatient prescriptions.

3. Please list the Ohio statute(s) that authorize the agency, board or commission to adopt the rule(s) and the statute(s) that amplify that authority.
The proposed rule is authorized by sections 4729.26, 4729.54, 4729.55 of the Ohio Revised Code.

4. **Does the regulation implement a federal requirement?** Is the proposed regulation being adopted or amended to enable the state to obtain or maintain approval to administer and enforce a federal law or to participate in a federal program?
   
   *If yes, please briefly explain the source and substance of the federal requirement.*

These rules do not implement a federal requirement.

5. **If the regulation includes provisions not specifically required by the federal government, please explain the rationale for exceeding the federal requirement.**

This rule package exceeds federal requirements because the regulation of the pharmacy profession and the distribution of dangerous drugs has traditionally been done at the state level by legislatively created state boards of pharmacy.

6. **What is the public purpose for this regulation (i.e., why does the Agency feel that there needs to be any regulation in this area at all)?**

Section 4729.26 of the Ohio Revised Code authorizes the Board of Pharmacy to adopt rules governing the practice of pharmacy and distribution of dangerous drugs. The rules proposed under this statutory authority are necessary to promote the public’s safety.

Without these regulations, the Board of Pharmacy would not be able to ensure that patients who have conditions such as malaria, rheumatoid arthritis, and lupus that are being treated with these medications do not experience shortages during the COVID-19 outbreak.

7. **How will the Agency measure the success of this regulation in terms of outputs and/or outcomes?**

The success of the regulation will be measured by having a rule written in plain language. Licensee/registrant compliance with the rule, and minimal questions from licensees/registrants regarding the provisions of the rules.

8. **Are any of the proposed rules contained in this rule package being submitted pursuant to R.C. 101.352, 101.353, 106.032, 121.93, or 121.931?**

   *If yes, please specify the rule number(s), the specific R.C. section requiring this submission, and a detailed explanation.*

No.

**Development of the Regulation**

9. **Please list the stakeholders included by the Agency in the development or initial review of the draft regulation.**

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The rule in this package was developed based off of feedback provided by the Ohio Pharmacists Association, the National Association of Retail Merchants, the Arthritis Foundation, and the Lupus Foundation of America.

10. What input was provided by the stakeholders, and how did that input affect the draft regulation being proposed by the Agency?

N/A

11. What scientific data was used to develop the rule or the measurable outcomes of the rule? How does this data support the regulation being proposed?

Scientific data utilized by the FDA’s emergency use authorization for these drugs was used to support the adoption of this regulation. The FDA permits the use of the drug for patients who “are hospitalized with COVID-19 for whom a clinical trial is not available, or participation is not feasible.”

12. What alternative regulations (or specific provisions within the regulation) did the Agency consider, and why did it determine that these alternatives were not appropriate? If none, why didn’t the Agency consider regulatory alternatives?

As the regulations are essential to protecting the public’s safety by ensuring patients with chronic conditions have access to these medications, the State of Ohio Board of Pharmacy did not consider any regulatory alternatives.

13. Did the Agency specifically consider a performance-based regulation? Please explain.

Performance-based regulations define the required outcome, but don’t dictate the process the regulated stakeholders must use to achieve compliance.

The agency did not consider a performance-based regulation for this rule package. It is the Board’s responsibility to ensure uniform standards across Ohio. At this juncture, it was the determination of the Board that the rule package did not lend itself to a performance-based regulations.

14. What measures did the Agency take to ensure that this regulation does not duplicate an existing Ohio regulation?

The Board of Pharmacy’s Director of Policy and Communications reviewed the proposed rule to ensure that the regulation does not duplicate another State of Ohio Board of Pharmacy regulation.

15. Please describe the Agency’s plan for implementation of the regulation, including any measures to ensure that the regulation is applied consistently and predictably for the regulated community.
The rule will be posted on the Board of Pharmacy’s web site, information concerning the rule will be included in materials e-mailed to licensees, and notices will be sent to associations, individuals and groups. Board of Pharmacy staff are also available via phone or email to answer questions regarding implementation of the rule. In addition, the Board’s compliance staff are trained to educate licensees on current and/or new regulations during on-site inspections.

Board of Pharmacy staff receive regular updates on rules via a monthly internal newsletter, biannual staff meetings featuring a regulatory update, mandatory all-day law reviews for new employees, email updates and webinars from the Director of Policy and Communications and feedback from the Board’s legal department for every citation submitted.

**Adverse Impact to Business**

16. Provide a summary of the estimated cost of compliance with the rule. Specifically, please do the following:
   
a. Identify the scope of the impacted business community; and

The rule package impacts the following:
- Pharmacists and Pharmacies
- Prescribers
- Patients who have conditions such as malaria, rheumatoid arthritis, and lupus that are being treated with these medications.

b. Identify the nature of all adverse impact (e.g., fees, fines, employer time for compliance); and

Violation of these rules may result in administrative discipline for a pharmacist. Discipline might include reprimand, denial of a license, suspension of a license, continuing education, monetary fine and/or revocation of a license.

c. Quantify the expected adverse impact from the regulation.

   *The adverse impact can be quantified in terms of dollars, hours to comply, or other factors; and may be estimated for the entire regulated population or for a “representative business.” Please include the source for your information/estimated impact.*

New:

- 4729-5-30.02 – The rule outlines the prescription requirements for prescribing chloroquine or hydroxychloroquine. The rule does not apply to inpatient prescriptions. There may be administrative costs for pharmacies and pharmacists associated with compliance if prescribers do not include the required documentation on prescriptions (i.e. requires the pharmacy to contact the prescriber to obtain a diagnosis code).
17. Why did the Agency determine that the regulatory intent justifies the adverse impact to the regulated business community?

The Board believes that the regulatory intent of the proposed rules is necessary in order to protect the health and safety of all Ohioans by ensuring patients with chronic conditions have access to these medications. Stakeholders are already reporting that rheumatoid arthritis and lupus “patients are forced to ration their medication or go without it altogether, placing them at risk for worsening disease.”

**Regulatory Flexibility**

18. Does the regulation provide any exemptions or alternative means of compliance for small businesses? Please explain.

These rules do not provide any exemptions or alternative means of compliance for small businesses. The law does not differentiate on the size of the business and therefore the regulation is uniform across Ohio.

19. How will the agency apply Ohio Revised Code section 119.14 (waiver of fines and penalties for paperwork violations and first-time offenders) into implementation of the regulation?

The State of Ohio Board of Pharmacy does not fine licensees or impose penalties for first-time paperwork violations. However, any failure of a standard of care in the practice of pharmacy or the distribution of dangerous drugs is not considered a paperwork error but a quality assurance issue by the licensee that is necessary for the protection of the public.

20. What resources are available to assist small businesses with compliance of the regulation?

Board of Pharmacy staff is available by telephone and e-mail to answer questions. Board staff members also provide presentations to groups and associations who seek updates on current regulations and host regional meetings to discuss changes to Ohio laws and rules. Additionally, staff are trained to educate licensees on compliance with all Board of Pharmacy rules and regulations.

Lastly, this rule is already in effect as an emergency rule and the Board has [developed an FAQ](#) to assist all licensees to ensuring compliance.
4729-5-30.2 Prescription requirements for chloroquine and hydroxychloroquine.

(A) Unless otherwise approved by the board's executive director, no prescription for chloroquine or hydroxychloroquine may be dispensed by a pharmacist or sold at retail by a licensed terminal distributor of dangerous drugs unless all the following apply:

(1) The prescription bears a written diagnosis code from the prescriber; and

(2) If written for a COVID-19 diagnosis, the diagnosis has been confirmed by a positive test result, which is documented on the prescription and both of the following apply:

(a) The prescription is limited to no more than a fourteen-day supply; and

(b) No refills may be permitted unless a new prescription is furnished.

(B) Prescriptions for either presumptive positive patients or prophylactic use of chloroquine or hydroxychloroquine related to COVID-19 is strictly prohibited unless otherwise approved by the board's executive director in consultation with the board president, at which time a resolution shall issue.