



# IBPE Petition for Waiver

State of Iowa

Submitted On:

August 10, 2020 3:09pm

America/New\_York

<b>Licensee/Registrant Name</b>	Genoa Healthcare, LLC
<b>License/Registration No.:</b>	Pending
<b>Address Autocomplete</b>	180 10th Street SE, Room P, Suite 201, Le Mars, IA 51031
<b>Contact Person for Petition for Waiver</b>	Dale Masten
<b>Direct Phone Number for Contact Person</b>	[REDACTED]
<b>Direct Email Address for Contact Person</b>	[REDACTED]
<b>List each rule you are requesting to be waived:</b>	657 Iowa Admin Code 657 13.16.(8) 10 mile distance rule
<b>Describe specifically which requirements you are requesting to be waived</b>	Tele pharmacy should be at least 10 miles from another licensed pharmacy that dispenses prescription drugs to outpatients. Genoa would have 3 pharmacies closer than 10 miles.
<b>Start Date</b>	8 26 2020
<b>End Date</b>	8 26 2022
<b>Have you previously requested a waiver of any of the rules listed above?</b>	No
<b>If so, what was the outcome?</b>	N/A
<b>Explain why following the rule would pose an undue hardship:</b>	(1) N/A The nearest licensed pharmacies are open to the general public and provide service to all disease states. While Genoa pharmacies fill all prescriptions, our pharmacies specialize in serving the severe and persistent mentally ill. Our services are specifically designed for this unique population. In partnership with Plains Area Mental Health Center, Genoa will service approximately 3000 unique patients in 10 Iowa counties.
<b>Explain how waiving the rule may impact other people:</b>	(2) Genoa is unaware of the service offered by the other pharmacies. However, severe and persistent mentally ill patients make up nearly 100% of Genoa's patient population. We provide more convenient access to Genoa pharmacy Services for those living with mental illness, services include: a. Convenience co located inside PAMHC other pharmacies do not offer this convenience, which will serve to increase medication adherence b. Adherence packaging c. Medication synchronization minimizes trips to pharmacy for those patients impacted by transportation issues d. Monthly personalized, non robotic refill reminder calls e. Prior authorization assistance, which decreases time patient has to wait for an approved medication

- f. Mailing and delivery services
  - g. Long Acting Injectable medication, which can be administered on site by clinic staff
  - h. Services catered to those with mental health/SUD
- (3) N/A Genoa's telepharmacy will provide services in partnership with Plains Area Mental Health Center which covers 10 Iowa counties and 14 locations.
- a. Counties include: Buena Vista, Carroll, Cherokee, Crawford, Greene, Ida, Monona, Plymouth, Sac and Sioux Counties.
  - b. PAMHC recently received Certified Community Behavioral Health Clinic grant from the Substance Abuse and Mental Health Services Administration.
  - c. List of how Genoa RDS can improve patient access
    - i.ii. Convenience co located inside PAMHC helps with adherence
    - iii. Adherence packaging
    - iv. Medication synchronization minimizes trips to pharmacy for those patients impacted by transportation issues
    - v. Monthly personalized refill reminder calls
    - vi. Prior authorization assistance, which decreases time patient has to wait for an approved medication
    - vii. Mailing and delivery services
    - viii. Long Acting Injectable medication, which can be administered on site by clinic staff
    - ix. Services catered to those with mental health/SUD
- Increase access to mental health pharmacy services in the ten counties.

**Explain how the rule is intended to protect the public health, safety, or welfare:**


- (4) Patient Safety increases patient safety:
- a. Integrated approach with clinic allows for a convenient way for patients to leave their appointments and receive medication
  - b. Prior Authorization assistance helps decrease time patient potentially goes without medication
  - c. Studies show over 30 percent of prescriptions go unfilled. Please see [https://www.aafp.org/news/health\\_of\\_the\\_public/20140428nonadherencestudy.html](https://www.aafp.org/news/health_of_the_public/20140428nonadherencestudy.html) Genoa's location creates convenient access to their medications.
  - d. Increased adherence. Less chance that patient's will go without medication Genoa adherence rate 96%
  - e. Genoa's monthly personalized non robotic refill reminder calls serve as another well check and helps ensure medication adherence
  - f. Michigan study included
    - i. Genoa's adherence rate is over 90%
    - ii. Shows 40% reduction in behavioral health related hospitalizations
    - iii. Shows 18% reduction in behavioral health related emergency room visits
- (5) The transportation barrier is due to Genoa's patient population. Genoa's patients are mainly Medicaid and Medicare patients. Typically these patients do not have their own transportation and in many cases must rely on other methods. A Genoa telepharmacy co located inside PAMHC decreases barriers due to transportation issues because
- a. Medications are available after appointments, within the same building as their appointment. Therefore, no additional trip is necessary
  - b. Medication synchronization less trips to pharmacy for those with transportation issues
  - c. Mail and delivery for those without transportation at no cost
    - i. USPS, courier, Fedex/UPS
- :

**Explain how the public health, safety, or welfare can still be protected if the rule is waived:**

(7) N/A However, in this area there is limited access to specialized mental health pharmacy services. Genoa's telepharmacy will be able to provide mental health pharmacy services to 10 Iowa counties where PAMHC is located.

**Have you spoken to a Board compliance officer or other member of Board staff about your request?**

Yes

<b>If so, who?</b>	Sue Mears, RPh
<b>Attach copies of any relevant email correspondence</b>	<a href="https://seam.ly/nnbvRxPA">https://seam.ly/nnbvRxPA</a> Email from Sue Mears.pdf
<b>Do you plan to attend the Board meeting when this Petition will be considered?</b>	Yes
<b>Attach any relevant documentation to support your answers.</b>	<a href="https://seam.ly/XB1DV2Xx">https://seam.ly/XB1DV2Xx</a> MI and Adherence Study.pdf
<b>Sign Here</b>	Dale Masten   <i>Dale Masten</i>  Signed at: August 10, 2020 2:06pm America/New_York
<b>Receipt</b>	0000022



# One in Three Patients Not Filling Prescriptions, Study Finds

## *Physicians Can Have Positive Impact on Primary Nonadherence*

April 28, 2014 09:19 am [Chris Crawford \(mailto:aafpnews@aafp.org\)](mailto:aafpnews@aafp.org) – Nearly a third of patients fail to fill first-time prescriptions, according to a study published April 1 in the *Annals of Internal Medicine* (<http://www.annals.org/article.aspx?doi=10.7326/M13-1705>). But attention to prescription costs and consistent follow-up with patients -- both factors that family physicians can address with their patients -- should help overcome barriers to adherence identified in the study, say the authors.

For the study, Canadian researchers evaluated the electronic health records of 15,961 patients in a primary care network that included 131 physicians to estimate the incidence of primary nonadherence (failure to fill a first-time prescription) and to ferret out which drug, patient and physician characteristics might be associated with nonadherence. Patients' health records were linked to insurer data on drugs dispensed by community-based pharmacies in relation to specific office visits.



The researchers found that slightly more than 31 percent of all initial drug prescriptions were not filled within nine months. Nonadherence was highest for expensive drugs and preventive therapies for chronic conditions such as ischemic heart disease and depression. In addition, patients with higher copayments, recent hospitalization and more severe comorbid conditions were at increased risk for nonadherence.

Among the researchers' other findings:

- Prescriptions for antibiotics were most likely to be filled.
- Patients who had more visits with the prescribing physician were more likely to fill their prescriptions.

- Older patients were less likely than younger individuals to be nonadherent; the odds of nonadherence dropped by 11 percent for each 10-year increase in age.

### STORY HIGHLIGHTS

- A study published April 1 in the *Annals of Internal Medicine* found that more than 31 percent of all first-time drug prescriptions were not filled within nine months.
- One solution the study authors offered as a means to improve prescription adherence was for prescribing physicians to enhance their patient follow-up efforts.
- The issue is not new to the AAFP, which partnered in the Prescriptions for a Healthy America coalition last spring to identify ways of improving medication adherence rates in the United States.

Physician gender and years in practice were factored into the analysis because these characteristics have previously been shown to influence prescribing decisions, as does physician-patient communication. However, no significant correlation between these characteristics and nonadherence was seen.

Although the study was conducted in Quebec, where the provincial insurance agency provides health insurance for all provincial residents and drug insurance to about 50 percent of all residents, the lessons it offers are relevant to prescription adherence behavior in the United States.

### Boosting Adherence Through Follow-up

One solution the study authors offered as a means to improve adherence was for prescribing physicians to enhance follow-up care -- a concept that is, of course, integral to the patient-centered medical home (<https://www.aafp.org/practice-management/transformation/pcmh.html>).

"From my perspective, the thing that stands out is the importance of regular follow-up and continuity of care," AAFP Health of the Public and Science Medical Director Jennifer Frost, M.D., told *AAFP News*. "This will hopefully improve as more practices become patient-centered medical homes.

"Family doctors should also remain aware of the effect of cost on compliance and, therefore, consider the cost of medication when choosing what to prescribe."

It's also worth noting that with the advent of electronic health records and e-prescribing, family physicians now can more readily access information that indicates whether patients are filling their prescriptions.

### Part of the Solution

Medication nonadherence is not a new issue for the AAFP. In May of last year, in fact, the Academy joined a coalition (<https://www.aafp.org/news/inside-aafp/20130507prescripcoalition.html>) of some 30 organizations dedicated to identifying ways to improve medication adherence rates in the United States. Stakeholders in the Prescriptions for a Healthy America (<http://adhereforhealth.org>) initiative include physician, pharmacy, health care industry and consumer groups.

During an event held to mark the coalition's launch, AAFP Director Rebecca Jaffe, M.D., M.P.H., of Wilmington, Del., called poor medication adherence a "leading driver of hospital admissions and readmissions" and the cause of at least 100,000 deaths a year.


According to Jaffe, six out of 10 patients do not take their medications as prescribed by their physicians. This information was based on a coalition-commissioned survey of patients in which respondents were also asked to identify possible ways to improve adherence rates.

Suggestions included increasing one-on-one communication between health care professionals and patients and providing clear information about medications. Survey respondents also suggested following up with patients via emails and by phone with a reminder to take their medications.

Visit the Prescriptions for a Healthy America website for more [proposed solutions](http://adhereforhealth.org/our-priorities/proposed-solutions/) (<http://adhereforhealth.org/our-priorities/proposed-solutions/>) to the dilemma of medication nonadherence, as well as [additional resources](http://adhereforhealth.org/resources/) (<http://adhereforhealth.org/resources/>) on the topic.

## 2 comments

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 [Sign In \(\)](#) to comment

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## One in Three Patients Not Filling Prescriptions, Study Finds

<https://www.aafp.org/news/health-of-the-public/20140428nonadherencestudy.html>

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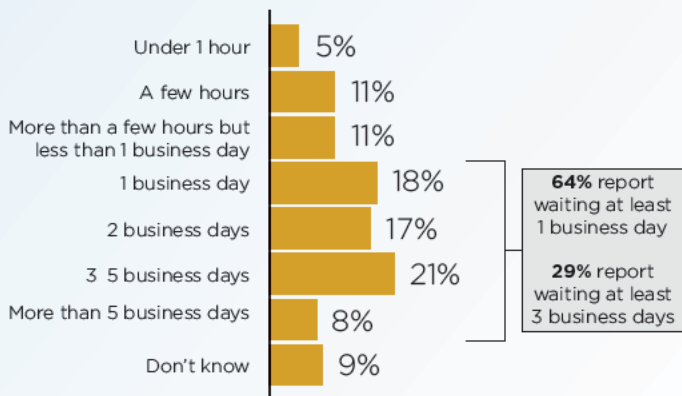
800.274.2237 • 913.906.6000 • Fax: 913.906.6075 • [aafp@aafp.org](mailto:aafp@aafp.org)

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## Patient impact

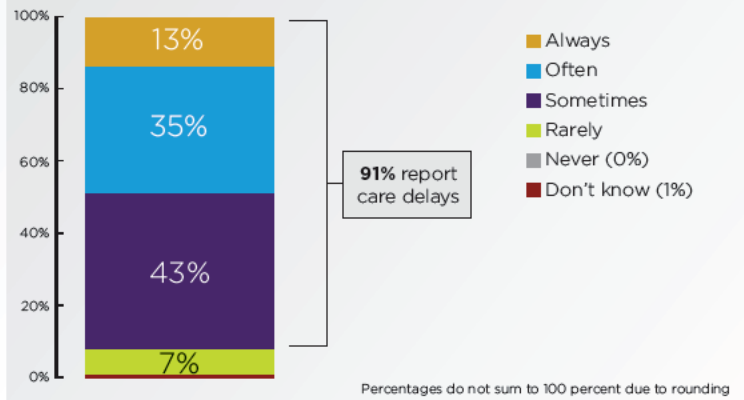
### Average wait time for PA responses

**Q:** In the last week, how long on average did you and your staff need to wait for a PA decision from health plans?



### Care delays associated with PA

**Q:** For those patients whose treatment requires PA, how often does this process delay access to necessary care?



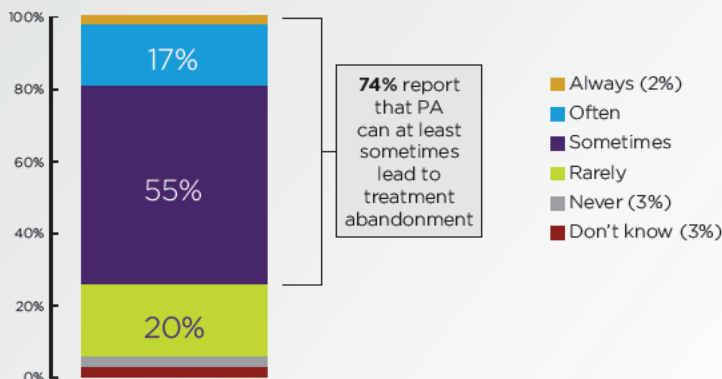
## PA and patient harm<sup>1</sup>

**24%** of physicians report that PA has led to a serious adverse event for a patient in their care.

**16%** of physicians say that PA has led to a patient's hospitalization.

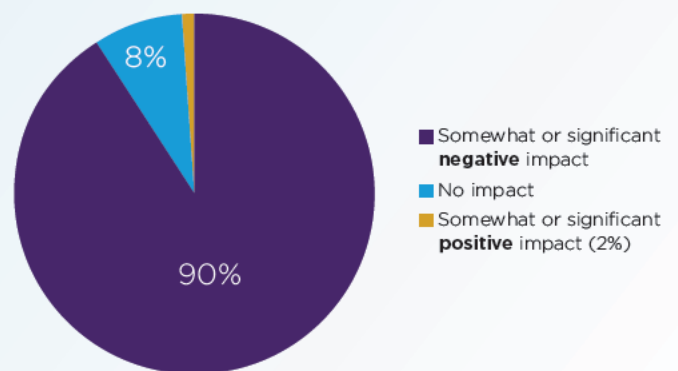
### Abandoned treatment associated with PA

**Q:** How often do issues related to the PA process lead to patients abandoning their recommended course of treatment?



### Impact of PA on clinical outcomes

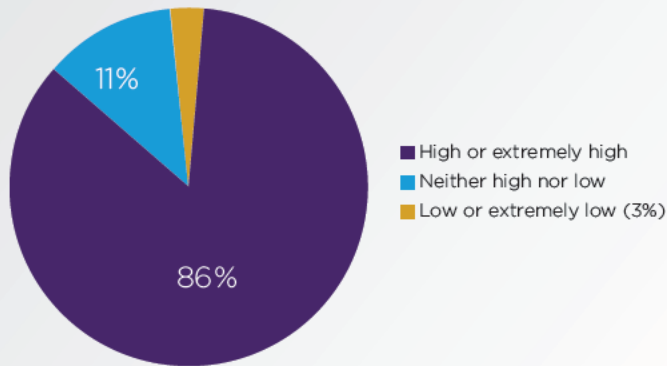
**Q:** For those patients whose treatment requires PA, what is your perception of the overall impact of this process on patient clinical outcomes?



# Physician impact

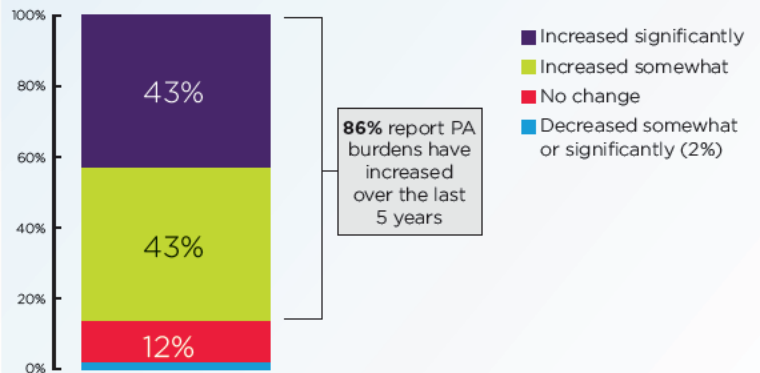
## Physician perspective on PA burdens

**Q:** How would you describe the burden associated with PA in your practice?



## Change in PA burden over the last five years

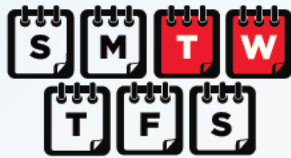
**Q:** How has the burden associated with PA changed over the last five years in your practice?



On average, practices complete

**33**  
PAs per physician, per week<sup>2</sup>

Physicians and their staff spend an average of almost



**two business days** (14.4 hours) each week completing PAs<sup>3</sup>



**Almost one-third**  
**30%**  
of physicians have staff who work exclusively on PA<sup>4</sup>

## Survey methodology

- Thirty one question, web based survey administered in December 2019
- Sample of 1,000 practicing physicians drawn from M3 panel
- Forty percent primary care physicians/ 60% specialists
- Sample screened to ensure that all participating physicians:
  - Are currently practicing in the United States
  - Provide 20+ hours of patient care per week
  - Complete PAs during a typical week of practice

## Survey questions

- 1. Serious adverse events:** In your experience, has the PA process ever affected care delivery and led to a serious adverse event (e.g., death, hospitalization, disability/permanent bodily damage or other life threatening event) for a patient in your care?
- 2. Number of PAs:** Please provide your best estimate of the number of prescription and medical services PAs completed by *you yourself and/or your staff* for your patients in the last week. Do not include PAs that practice staff completed for the patients of other physicians in your practice.
- 3. Time to complete PAs:** Thinking about all of the PAs you and your staff completed in the last week, please provide your best estimate of the number of hours spent on processing these PAs. Do not include PAs that practice staff completed for the patients of other physicians in your practice.
- 4. Practice resources for PA workload:** Do you have staff members in your practice who work exclusively on PA?

For information on the AMA's advocacy efforts and resources to reduce PA burdens, visit [ama-assn.org/prior-auth](http://ama-assn.org/prior-auth).

To join the AMA's grassroots PA reform campaign and sign a petition to Congress, visit [fixpriorauth.org](http://fixpriorauth.org).





## Kunz, Joy

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**From:** Cox, Tammy  
**Sent:** Thursday, July 30, 2020 2:41 PM  
**To:** Kunz, Joy  
**Subject:** FW: Petition for Waiver

I received this email from the IA Board of Pharmacy -- I did not do anything with it but forward it to you

Tammy Cox, PharmD  
Site Manager, #20304 [Genoa Healthcare](#)  
Located Within: Siouxland Mental Health Clinic  
Phone: 712-266-3956 Fax: 712-560-7618  
625 Court Street Ste P Sioux City, IA 51101

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**From:** Mears, Sue <sue.mears@iowa.gov>  
**Sent:** Thursday, July 30, 2020 2:14 PM  
**To:** Cox, Tammy <tc Cox@genoahealthcare.com>  
**Cc:** Andrew Funk <andrew.funk@iowa.gov>  
**Subject:** Petition for Waiver

**\*\*External Sender\*\***

Hi, Tammy -

Your petition for waiver to the distance requirement for a telepharmacy in Le Mars was forwarded to me for review. There are several issues with the petition and it will need to be resubmitted, correcting the issues, before it can be added to the Board's agenda.

1. The Board has a new online petition form that should be used - click [HERE](#).
2. The petition did not identify a requested end date.
3. The answer to the hardship that complying with the rule would cause was inadequate. If the Board denied the distance request, then the pharmacy would have to be licensed as a general pharmacy with an on-site pharmacist present at all times when the pharmacy is open. (Side note, the pharmacy's application indicates there would be 160 pharmacist hours per month, so that would seem to indicate the Le Mars location would have a full time pharmacist there, so it's unclear why a telepharmacy license is being sought.) The applicant needs to establish why licensing the pharmacy as a general pharmacy with an on-site pharmacist would pose an undue hardship.
4. The answers to the two questions that ask about public protection are also inadequate.
5. The petition requires that you identify which rule you are seeking a waiver from. The petition was submitted with a subsection of Iowa Code. Please identify and include the rule(s) or subrule(s) from 657 Iowa Administrative Code that you are seeking waiver from.
6. The petition did not provide adequate information about the justification for a telepharmacy within 10 miles of the nearest pharmacy. The board's rules provide a list of justifications that must be

answered for the Board to consider. See 657-13.16(8). These must be included in any petition for waiver to the distance requirement.

If you would like the Board to consider a newly submitted petition for the distance requirement, a completed petition must be submitted by August 11.

Let me know if you have any questions,

**Sue Mears, RPh**

Compliance Officer | Iowa Board of Pharmacy | 400 S.W. 8th Street, Suite E | Des Moines, Iowa 50309 | 515-408-7824 (cell) | 515-281-4609 (fax) | [sue.mears@iowa.gov](mailto:sue.mears@iowa.gov)

The Iowa Board of Pharmacy promotes, preserves, and protects the public health, safety, and welfare through the effective regulation of the practice of pharmacy and the licensing of pharmacies, pharmacists, and others engaged in the sale, delivery, or distribution of prescription drugs and devices or other classes of drugs or devices which may be authorized. Iowa Code § 155A.2(1).

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