



## Use of Pharmacy Text Messaging Capabilities in a Future Pandemic

A potentially powerful resource for public health, but obstacles must be proactively addressed

Automated communications to patients is a capability widely utilized by pharmacies in the United States to increase medication adherence<sup>i</sup>. The majority of pharmacy messaging programs offer refill reminder services via text, automatic phone call, app notification and/or email, depending on the patient's preferences. This type of message that the patient receives is not under the direct control of the pharmacy staff, but rather automated based on the prescription order details. Most commonly, patients opt into refill reminder services at the point of service at the pharmacy at the prompting of the pharmacist or technician, but may also have the option to opt in using the pharmacy's website, interactive voice response system or via a mobile application. Additional (optional) services that may be offered to pharmacy patients include:

- pickup reminders for filled prescriptions,
- patient-directed refill ordering services,
- mobile payments,
- access to patient profile history,
- links to information on medications or other health resources,
- dose reminder notifications,
- logs for relevant information (such as blood pressure or blood glucose measurements), or even
- attaining financial incentives for healthy behaviors.

All of these are part of community pharmacy's multi-layered strategies to increase health through medication and non-pharmacological treatment adherence. Each company's messaging system is unique, as is the extent of implementation and integration with their dispensing databases.

It is easy to imagine that these tools could be put to great use in a future pandemic or other public health emergency to communicate important messages or reminders to the general public. It would be especially powerful to have the ability to target messages to those who might be most vulnerable. One could picture a scenario where response managers knew that asthmatics and pregnant women were particularly high-risk for life-threatening complications of a currently circulating influenza strain, and were then able to target specific, action-oriented messages to patients whose recent profile includes inhalers or prenatal vitamins. Of course, that specialized capability could not be developed *ad hoc* at the time of



an emergency, but rather purpose-built prior to the occurrence, and adapted for the specific parameters of the incident. But as things stand now, even though it is easy to imagine many other uses for this kind of capability that could improve the health of patients, the business case for spending the resources for development of that kind of capability remain uncertain.

Leaders of pharmacy businesses envision pharmacies as healthcare providers first, and businesses second<sup>ii</sup> - this is represented even in the tagline for the association that represents US chain drug stores, the National Association for Chain Drug Stores (NACDS): "*Pharmacies. The face of neighborhood healthcare.*" However, business risks and concerns do have to factor into decision making that could affect the ability of the company to continue to operate. Relevant to this discussion are the restrictions and regulations pertaining to automated communications within the privacy and security protections defined by the [Health Insurance Portability and Accountability Act of 1996](#) (HIPAA) and the consumer protections of the [Telephone Consumer Protection Act](#) (TCPA).

HIPAA requires health care providers (among others) ensure that personally identifiable health information (PHI) is both protected from inappropriate disclosure (this is known as the [Privacy Rule](#)) and securely stored, accessed and transmitted electronically (known as the [Security Rule](#)).<sup>iii</sup> Disclosures that are made outside of permitted reasons such as treatment or payment or allowed exemptions require the patient's permission. Failure to protect PHI may result in severe penalties. Communications that do not involve direct, real-time communication between the provider and the patient may result in a non-permitted disclosure of PHI. For example, a provider cannot ensure that a voicemail, text message or automated message will be accessed only by the intended recipient. Thus, these forms of communication are required to be non-specific and may not result in the desired action by the patient. The Privacy Rule does have an exemption that allows for refill reminders,<sup>iv</sup> but it is unclear whether a follow up dose in a vaccination series qualifies as a refill under this exemption. Additionally, the exemption as it is written (and currently interpreted) most likely would not include preemptive messages suggesting new treatment, such as the initiation of a vaccination series. Of course, patients can give permission to a pharmacy or other messaging provider to receive health messages, but that limits the utility of having the capability to message a broad audience for an emergency situation – such as a pandemic.

Another, more concerning, obstacle to the use of automated communications to deliver public health emergency notifications involves the TCPA. The TCPA was



originally passed in 1991 and was intended to protect consumers from unwanted communications via telephone and fax<sup>v</sup>. As mobile technologies have expanded, the TCPA protections have also been expanded to include calls to cell phones, text messages and email communications. An unintended consequence of the TCPA provision is that implementation of automated communications intended to increase medication adherence and improve health have resulted in consumer complaints to the FCC that these communications violate the TCPA protections. So, even while HHS is facilitating refill reminder communications intended to improve medication adherence through the HIPAA exemption, the FCC, through TCPA implementation, has discouraged full utilization of these systems, resulting in costly fines and settlements from pharmacies.<sup>vi</sup>

In 2015, the [FCC issued document 15-72](#)<sup>vii</sup> which was intended to clarify some of the issues that left pharmacies or other healthcare providers vulnerable to punitive action, including issues pertaining to messages sent to a phone number that had been transferred from one user to another, resulting in unwanted messages for the new phone user. While the guidance has provided some clarity in that it allows for refill reminders, it did not go far enough to provide reassurance to providers that refill reminder systems can be feasibly implemented without violating the intent of consumer protection regulations.<sup>viii</sup> There is also concern that some of the provisions required in 15-72, such as ensuring that any messages sent will be at no cost to the consumer, are not practically achievable. Because of these concerns and lingering uncertainties, the National Association of Chain Drug Stores (NACDS) has filed an amicus brief<sup>ix</sup> in support of refill reminders and continued use of messaging platforms for providing healthcare communications.

With this much uncertainty pertaining to communications that are as clearly beneficial as refill reminders, then the applicability of TCPA to novel communications such as vaccine reminders or other public health messaging are even less clear. Indeed, CVS has been sued for providing messages announcing availability of influenza vaccine, which were interpreted as marketing messages rather than exempt healthcare messages<sup>x</sup>. TCPA also allows for emergency communications, but the FCC has not defined what it considers an emergency for these purposes, with one exception: refill reminders are not considered an emergency<sup>xi</sup>. During the 2009 H1N1 pandemic, the first wave response and the vast majority of messaging and planning occurred without a presidential emergency declaration at the national level – the pandemic began in April 2009, yet the presidential declaration of a national emergency was delayed until October 2009.<sup>xii</sup> Without further guidance from the FCC, the uncertain nature of what is



considered an emergency to allow delivery of messages without prior consent may be ill-advised, particularly for a large company that might be vulnerable to class-action litigation from their millions of patients. It would be very appealing from a risk manager's perspective for an agency, such as CDC, to have vetted with the FCC the healthcare or emergency nature of the communications CDC would like to ask pharmacies to send to their patients<sup>xiii</sup>.

Public health agencies are not exempt from HIPAA,<sup>xiv</sup> although the risk of costly fines is likely much lower for a public agency than a for-profit company such as a national pharmacy chain. It is also unclear whether immunity from litigation under TCPA would apply to a government contractor,<sup>xv</sup> so if CDC or another public health agency decided to implement their own text messaging system, there may be some limitations that apply to how messages are approved and sent. Another consideration to ponder for a CDC-directed messaging outreach is that the extent of messaging that will be needed to respond to a global pandemic may be likely to trigger many complaints to HHS and the FCC, enough to warrant a response from those regulatory agencies.

In conclusion, there is tremendous potential for the use of existing communications tools that can reach vulnerable populations in a time of a healthcare emergency. And while there are obstacles to full utilization of those capabilities, they are not insurmountable. Pharmacies are healthcare providers that want to provide the best care for their patients – while staying in business to be able to continue to provide care. A coordinated planning effort that brings in not just CDC and pharmacy companies, but also the HIPAA and TCPA regulators into the planning process will help ensure that these capabilities can and will be built and available to use in a future response.



## Endnotes

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<sup>ii</sup> Daly, M., Andreozzi, B., & Kay, J. (2016, February 26). Interview with Michael Daly, Bradley Andreozzi, and Justin Kay of Drinker Biddle [Telephone interview].

<sup>iii</sup> HHS. (n.d.). HIPAA for Professionals. Retrieved February 27, 2016, from <http://www.hhs.gov/hipaa/for-professionals/index.html>

<sup>iv</sup> HHS. (n.d.). The HIPAA Privacy Rule and Refill Reminders and Other Communications about a Drug or Biologic Currently Being Prescribed for the Individual. Retrieved February 27, 2016, from <http://www.hhs.gov/hipaa/for-professionals/privacy/guidance/refill-reminders/>

<sup>v</sup> FCC. (2015, November 20). Telemarketing and Robocalls. Retrieved February 27, 2016, from <https://www.fcc.gov/general/telemarketing-and-robocalls>

<sup>vi</sup> LaFreniere, M. (2015, April 8). Judge Prelim. Approves \$11M Walgreens Pharmacy Robocall Class Action Settlement [Web log post]. Retrieved February 27, 2016, from <http://topclassactions.com/lawsuit-settlements/lawsuit-news/53331-judge-prelim-approves-11m-walgreens-pharmacy-robocall-class-action-settlement/>

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<sup>vii</sup> FCC. (2015, June 18). *FCC STRENGTHENS CONSUMER PROTECTIONS AGAINST UNWANTED CALLS AND TEXTS* [Press release]. Retrieved February 27, 2016, from [https://apps.fcc.gov/edocs\\_public/attachmatch/DOC-333993A1.pdf](https://apps.fcc.gov/edocs_public/attachmatch/DOC-333993A1.pdf)

<sup>viii</sup> NACDS files legal brief in support of cell phone refill reminders [Web log post]. (2015, December 4). Retrieved February 27, 2016, from <http://www.pharmacist.com/nacds-files-legal-brief-support-cell-phone-refill-reminders>

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<sup>ix</sup> NACDS. (2015, December 2). *BRIEF AMICUS CURIAE OF THE NATIONAL ASSOCIATION OF CHAIN DRUG STORES, INC. IN SUPPORT OF PETITIONER RITE AID HDQTRS. CORP*



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<sup>x</sup> Thompson v. CVS Pharmacy, Inc. (Florida Middle District March 26, 2016), PlainSite 6:14-cv-02081.

<sup>xi</sup> <http://topclassactions.com/lawsuit-settlements/lawsuit-news/53331-judge-prelim-approves-11m-walgreens-pharmacy-robocall-class-action-settlement/>

<sup>xii</sup> CDC. (2010, January 16). The 2009 H1N1 Pandemic: Summary Highlights, April 2009-April 2010. Retrieved February 27, 2016, from <http://www.cdc.gov/h1n1flu/cdcresponse.htm>

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<sup>xiii</sup> Daly, M., Andreozzi, B., & Kay, J. (2016, February 26). Interview with Michael Daly, Bradley Andreozzi, and Justin Kay of Drinker Biddle [Telephone interview].

<sup>xiv</sup> Karasz, H. N., Eiden, A., & Bogan, S. (2013). Text Messaging to Communicate With Public Health Audiences: How the HIPAA Security Rule Affects Practice. *Am J Public Health American Journal of Public Health*, 103(4), 617-622. doi:10.2105/ajph.2012.300999

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