

Medication Synchronization and the Appointment-Based Model

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Medication synchronization is a pharmacy service that improves patient adherence to prescribed medications by coordinating the refill dates for all of a patient's chronic prescription medications so they can be picked up on the same date each month. It is estimated that 21 percent of Americans use three or more medicines and 10 percent take five or more medicines. Using multiple medications increases with age, with almost 40 percent of U.S. adults aged 65 using five or more medicines.ⁱ Patient and caregiver lives are simplified by eliminating multiple trips to the pharmacy each month. It also minimizes confusion over when a prescription is due to be refilled, and minimizes disrupting treatment through delayed or missed refills.

The Appointment-Based Model (ABM) is a voluntary medication synchronization prescription refill program that aims to improve patient adherence as well as the efficiency of the pharmacy operation. The ABM provides enhanced patient access through a streamlined process, opportunity for patient education on medication use, and greater pharmacist oversight to address potential contraindications, duplicate drug therapy and errors.

Benefits of Medication Synchronization and the Appointment-Based Model (ABM)

- ✓ The avoidable costs resulting from nonadherence to medications is \$105 billion, with a range of \$68 billion to \$146 billion.ⁱⁱ
- ✓ The number of prescriptions and/or the number of doses of medication patients must take per day are contributing factors to nonadherence.ⁱⁱⁱ Poor adherence increases with the number of medications a patient is taking. This is especially relevant to chronically ill patients, who often take more than one medication to manage their conditions.^{iv}
- ✓ Chronic diseases and conditions, including heart disease, stroke, cancer and diabetes, are among the most common health problems. As of 2012, about half of U.S. adults, 117 million people, have one or more chronic health conditions, and one in four adults have two or more chronic health conditions.^v
- ✓ Patient self-reported adherence barriers include cost, convenience, lack of symptoms and poor information.^{vi}
- ✓ Use of medication creates downstream medical offsets. A recent study showed that for the four chronic conditions representing 40 percent of Medicare Part D utilization (dyslipidemia, hypertension, diabetes and congestive heart failure), medical offsets for a 1 percent increase in medicine use could be three to six times higher than the Congressional Budget Office's estimate of 0.2 percent.^{vii}
- ✓ .When medication synchronization was implemented by a large regional chain pharmacy, the following adherence improvement was observed across a range of chronic conditions.^{viii}
 - Program patients had 3.4 to 6.1 times greater odds of adherence compared with control patients.
 - Control patients were 52 percent to 73 percent more likely to stop taking their chronic medications over one year.
 - Enrolled patients met or exceeded the Centers for Medicare and Medicaid Services (CMS) 80 percent adherence threshold in all five measured drug classes.

- Patients, on average, used an additional 84 days of medication per patient per prescription per year.
- ✓ Medicare Part D insurance plan providers are required to accommodate prorated co-pays to patients and the CMS, in part to improve adherence to chronic medications. CMS estimates that the estimated cost of not filling first prescriptions for chronic medications results in an estimated \$1.9 billion cost to the system. Thus, CMS feels that if any small administrative costs are incurred, these are more than offset by avoiding other medical costs resulting from poor adherence.⁹
- ✓ CMS is also clear in stating that any administrative costs incurred granting short fills are countered with improved pharmacy operations.^{ix}

Questions and Answers

1. What outcomes are seen following the implementation of medication synchronization?

- Improved adherence and time on therapy.
 - The Thrifty White pharmacy chain has implemented pharmacy synchronization in 178 locations (nine states, more than 200,000 patients). Patients enrolled in the program have experienced 3.4 to 6.1 times greater odds of adherence.^x
 - An initial National Alliance of State Pharmacy Associations' pilot study shows 57 percent of the nonpersistent patients became persistent after 12 months in the ABM.^{xi}
- Enhanced patient quality of care resulting from better adherence and understanding of medication therapy.
- Increased patient and pharmacist engagement allowing for greater monitoring and oversight of patient multiple-medication regimens.
- More efficient pharmacy operations. Medication synchronization has the potential to reduce administrative costs incurred by pharmacists and physicians long term, as it streamlines medicine refill processes and helps pharmacies manage their inventories.^{xii}

2. Will this model increase utilization of generic medications?

No. Increased generic medication prescribing is not anticipated as a result of medication synchronization programs. The generic share of U.S. prescription medicines stands at 86 percent in 2013, and the IMS Institute for Healthcare Informatics predicts the generic market share has almost reached its maximal point.^{xiii} This program focuses on enhancing patient services with the goal of increasing adherence to prescribed treatments; the program does not impact existing state generic substitution laws.

3. Are pharmacists incentivized to switch medications?

No. Therapeutic switching is not part of the pharmacy synchronization model. State law dictating therapeutic switching has not changed and still requires authorization from the prescriber.

4. What if the patient cannot pay all of the co-pays at the same time?

Medication synchronization will allow patients to have a more predictable out-of-pocket cost each month so that they can better anticipate their medication expenses and budget accordingly. Programs are sufficiently flexible to accommodate a patient's financial situation by having two pickup dates if needed. Ultimately, synchronization programs are voluntary, and if patients do

not feel that the program is the best option for them, either for financial or other reasons, then they do not have to participate.

5. *What if the patient is using multiple pharmacies?*

This program helps reduce the burden on patients when they have several medications to treat chronic conditions at one pharmacy; it has no impact on patients who use multiple pharmacies. However, having an ABM in place should encourage patients to use a single pharmacy, thus improving patient outcomes by removing the burden on patients to manage complex medication regimens and by eliminating unnecessary trips to the pharmacy.

6. *What if the due dates of refills are not the same for all of the medications?*

Pharmacists work with the prescribing physician to ensure all of the refills are authorized and amounts are adjusted to accommodate medication synchronization. This could include partial prescription medicine refills to coordinate prescription refills across multiple medications. This process supports productive pharmacist and physician dialogue.

7. *What happens when there are dosage changes?*

Pharmacists work with the prescribing physician prior to the patient's pharmacy appointment to adjust doses, medication types, etc. This is no different than the currently established standard of practice.

8. *Does medication synchronization apply to controlled substances?*

Medication synchronization may include controlled substances, but typically synchronization will only apply if a controlled substance is used for chronic condition treatment. Medication synchronization programs do not change existing federal or state prescribing laws. For example, federal law prohibits the issuance of refills of Schedule II drugs; thus, synchronization programs cannot authorize refills of Schedule II drugs without a legitimate prescription. Additionally, patients participating in these programs receive monthly calls and check-ins from the pharmacists to ensure patients are appropriately taking their medications. This provides the pharmacist another opportunity to advise patients on the appropriate use of medications and potentially address misuse of such medicines.

9. *How are co-pays adjusted for partial refills?*

Currently, it is up to the discretion of the insurance companies to prorate patient cost sharing for partial refills. Pharmacies implementing medication synchronization programs have highlighted that insurer policies can be an obstacle for some patients. Medicare Part D has acknowledged this issue as well, and as of January 2014, Part D plans must establish a daily cost-sharing rate for certain prescriptions dispensed by a network pharmacy for less than a 30-day supply. The direction provided in the Final CMS 2014 Call Letter^{xiv} calls for the following calculation.

“In preparing bids for CY 2014, sponsors should take note that, in the case of a copayment, there will be a mandatory daily copayment field in the PBP for any tier where the plan has a copayment included in the cost sharing. The maximum amount that can be entered for the Daily Copayment field will be based on the one-month copayment amount divided by the actual number of days entered for that one month supply for that specific tier.

“For example: If a plan enters a 31 day supply as a one-month supply and a one-month copayment of \$35 for Tier 1, then the Daily Copayment entered for that tier cannot be higher than \$1.12. ($\$35/31=\1.129). This data entry validation is to assist plans in complying with the requirement that the daily copayment cannot be an amount that would require the enrollee to pay more for a month’s supply of the prescription than would otherwise be the case. Where a plan must round to a dollar and cents figure, the highest amount the plan could round to would be the nearest lower dollar and cents amount, as shown in the example.”

According to The National Council for Prescription Drug Programs (NCPDP), the Submission Clarification Code (SCC) 47 – Shortened Days’ Supply Fill – is used to alert the insurer that a prescription is for a shortened supply, and SCC 48 – Fill Subsequent to Shortened Days’ Supply Fill – is used to request an override to plan limitations when a fill subsequent to a shortened days’ supply is used to help with “too soon” refill rejects.

Prime Therapeutics, a national pharmacy benefit manager covering over 25 million lives, offers the following approach to adjust for daily patient cost sharing and medication synchronization:^{xv}

- Submit SCC 47 when the prescription is less than a 30-day supply.
- The Covered Person co-pay will be prorated based on the day supply and the daily cost sharing rate.
- Submit SCC 48 for subsequent fills to override the Refill Too Soon Edit.

10. Why is legislation needed?

Despite the benefits of synchronization, patients and pharmacies still face some challenges when trying to synchronize all of a patient’s prescriptions. A short fill or partial fill is often needed to align the patient’s medications to a single refill date. If payers do not have payment policies in place to provide coverage for a claim for less than a 30-day supply, then patients may be required to pay a full month’s co-pay for a few days’ supply. Just as Medicare Part D began to require daily cost-sharing rates for certain prescriptions dispensed, legislation is needed to ensure other payers also grant prorated cost sharing. Legislation also helps ensure that insurers can accommodate all interested patients since many of the prorated co-pays are being handled on an ad hoc basis.

11. Is the medical community in support of medication synchronization programs?

Yes. The American Medical Association adopted Resolution 801(I-12) in 2013, which encouraged relevant organizations, including insurance companies, to implement prescription refill strategies for patients with multiple prescriptions to reduce travel barriers to access to medicines.^{xvi}

12. Is the pharmacy community in support of medication synchronization programs?

Yes. Several national pharmacy associations are working to advance the adoption of medication synchronization. The National Community Pharmacist Association (NCPA) has an extensive effort behind their campaign called “Simplify My Meds,” with ABM at the center of this work.^{xvii} The American Pharmacists Association (APhA) Foundation has a multichannel initiative named “Align My Refills”, which includes patient outreach materials and a pharmacy locator to help patients find pharmacies offering medication synchronization services. The APhA

Foundation is also conducting research to provide additional evidence for how ABM benefits patients.^{xviii} The National Alliance of State Pharmacy Associations (NASPA) similarly features many of their own and other association resources on medication synchronization.^{xix} Lastly, the National Association of Chain Drug Stores (NACDS) forwards medication synchronization information to their members.

NCPA and NACDS have combined legislative efforts and have issued model language for reducing hurdles to medication synchronization in the states. This legislation is available by request and seeks to ensure that short fills needed to synchronize a patient's chronic medication refills have prorated daily cost-sharing rates for consumers and that pharmacists' dispensing fees are not reduced.

This year, the National Association of Boards of Pharmacy Task Force on Medication Synchronization recommended that the Executive Committee approve amending the Model Act to allow pharmacists limited refill authority to adjust refills at a patient's request in order to synchronize their medications for pick-up on the same day every month.^{xx} Even if this regulation moves forward, medication synchronization legislation is needed to ensure that short fills for aligning medications allow for prorated patient co-pays for daily cost sharing and keeping pharmacists' dispensing fees whole.

ⁱ Centers for Disease Control and Prevention, <http://www.cdc.gov/nchs/data/abus/abus13.pdf#092>.

ⁱⁱ IMS Institute. Avoidable Costs in U.S. Healthcare. June 2013. Available at http://www.imshealth.com/deployedfiles/imshealth/Global/Content/Corporate/IMS%20Institute/RUOM-2013/IHII_Responsive_Use_Medicines_2013.pdf.

ⁱⁱⁱ A.J. Claxton et al. "A Systematic Review of the Associations Between Dose Regimens and Medication Compliance." *Clinical Therapeutics*, August 2001.

^{iv} S.D. Saini et al. "Effect of Medication Dosing Frequency on Adherence in Chronic Diseases." *American Journal of Managed Care*, June 2009.

^v Centers for Disease and Prevention, <http://www.cdc.gov/chronicdisease/overview/index.htm>.

^{vi} New England Healthcare Institute. Thinking Outside the Pill Box: A System-wide Approach to Improving Patient Medication Adherence for Chronic Disease, 2009.

^{vii} Federal Register / Vol. 77, No. 71 / Thursday, April 12, 2012 / Rules and Regulations.

^{viii} Holford, D. et al. Appointment Based Model (ABM) 12 Month Data Analysis Report. Virginia Commonwealth University School of Pharmacy, January 2013.

^{ix} Centers for Medicare and Medicaid, Final Rule with Comment Period, Federal Register / Vol. 77, No. 71 / Thursday, April 12, 2012 / Rules and Regulations, related sections, 423.100, 423.104 and 423.153.

^x David A. Holdford and Timothy J. Inocencio, Journal of American Pharmacists Association, Adherence and persistence associated with an appointment-based medication synchronization program, <http://japha.org/article.aspx?articleID=1765641>.

^{xi} American Pharmacists Association Foundation White Paper found at National Alliance of State Pharmacy Associations, http://www.naspa.us/documents/grants/abm/2013-0923_ABMWhitePaper-FINAL.pdf.

^{xii} American Pharmacists Association Foundation White Paper, http://www.naspa.us/documents/grants/abm/2013-0923_ABMWhitePaper-FINAL.pdf.

^{xiii} IMS Institute for Healthcare Informatics, April 2014, Medicine Use and the Shifting Costs of Healthcare, <http://www.imshealth.com/ims/Global/Content/Insights>.

^{xiv} Centers for Medicare and Medicaid, Final 2014 Call Letter <http://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Announcement2014.pdf>.

^{xv} http://primetherapeutics.com/Files/3833_PrimePerspective_4Q2013.pdf.

^{xvi} <http://www.mag.org/sites/default/files/downloads/2012-ama-anno-rcr-j.pdf>.

^{xvii} <http://www.ncpanet.org/membership/benefits/preview-of-simplify-my-meds-/medication-synchronization>

^{xviii} <http://www.aphafoundation.org/align-my-refills>

^{xix} <http://www.naspa.us/grants/abm.html>

^{xx} http://www.nabp.net/system/rich/rich_files/rich_files/000/000/816/original/medsynchtfreport-final.pdf