

# Perspectives and Updates on Health Care Information Technology

# HIT Perspectives

- 1** **Part 1:** Following What the Doctor Ordered: Addressing Medication Noncompliance
- 2** **Part 2:** The Impact of New, Nonproprietary Naming Convention for Biologics and Biosimilars: 7 Key Findings
- 3** **Part 3:** ONC to Significantly Scale Back EHR Certification and Enforcement

## About the Newsletter

*HIT Perspectives* is published by Point-of-Care Partners. Individuals at the leading management consulting firm assist healthcare organizations in the evaluation, development and implementation of winning health information management strategies in a rapidly evolving electronic world. The team of accomplished healthcare consultants, core services and methodologies are focused on positioning organizations for success in the integrated, data-driven world of value-based care.

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# 1 Part 1: Following What the Doctor Ordered: Addressing Medication Noncompliance



By **Tony Schueth**,  
Editor-in-Chief

All prescriptions instruct patients to take a medication as directed, yet millions of Americans fail to follow through. About half of the 3.2 billion annual prescriptions dispensed in the United States are not taken as prescribed, and that number is even lower for patients with chronic conditions. The toll on patients and the health care system is staggering. According to recent [estimates](#), medication nonadherence causes some 125,000 deaths, untold disabilities, as well as 10% to 20% of hospitalizations and nursing home admissions each year. This adds up to between \$100 billion and \$289 billion annually. To be sure, medication noncompliance is a long-standing issue. Now we have reached an inflection point where technology, new care models, value-based purchasing and concerns about the costs of chronic illness are converging to meaningfully address the problem.

## Drivers for Change.

Several drivers are motivating stakeholders to address medication adherence at this time. They include:

### • Costs of noncompliance for chronic illness.

As mentioned previously, the overall costs of non-adherence are significant. They also are significant for individual chronic diseases, which are on the rise. Take costs associated with diabetes, which is one of the most common chronic conditions. According to [ExpressScripts](#), diabetics who were noncompliant with their oral diabetes drugs had 1.3 times higher medical costs and 4% higher total health care expenditures compared with those who were adherent. Put another way, annual spending on compliant diabetics was at least \$500 less than for nonadherent

patients, which extrapolates to an estimated \$210 million in savings for 2016. This kind of savings potential grabs the attention of policy makers, payers and providers.

### • New care models.

Medical care is moving toward a patient-centered, team approach, which includes nurses, care managers, pharmacists and other clinicians. These teams engage patients in their care and offer guidance and support as patients move along the care continuum. The team approach can help patients understand their disease and importance of taking their medications as directed, thus motivating them to be compliant and stay on therapy. Pharmacists' roles are expanding to include patient counseling with the objective of improving medication compliance. Increasing efforts to pay pharmacists for such services can ultimately have a positive impact on adherence.

### • Value-based contracting.

Value-based contracting is becoming more common. These arrangements reimburse providers for lower costs, better outcomes and fewer hospitalizations. As a result, medication adherence is becoming both a quality and outcomes measure in accountable care and performance-based contracting, including the Medicare star ratings program. Moreover, the potential savings resulting from improved medication compliance can incent physicians participating in value-based and pay-for-performance arrangements to take a more active role in identifying and addressing adherence.

- **Technology.**

Technology is now available to better share patient information and help identify and monitor noncompliant patients. For example, formulary and benefit information at the point of electronic prescribing (ePrescribing) can help physicians prescribe affordable medications covered by the patient's health plan. Prescription price is important because a significant number of prescriptions are not picked up once patients learn how much they will cost, or patients will halve or skip doses to save money. The RxFill function can indicate whether a patient filled or refilled a given medication, which could indicate compliance. Reports can be run on electronic health records (EHRs) to identify potentially noncompliant patients. In addition, there is a wide range of wearable, mobile and other devices to help patients improve medication adherence. Examples include smart pill bottles, mobile applications (such as text messages and pill alarms) and ingestible pill sensors.

## Moving forward.

There are many innovative opportunities to address medication adherence in a meaningful way. For example:

- **Going beyond reminders.**

Forgetfulness is a major contributor to nonadherence. Oral and written medication reminders can help, as well as wearable and mobile reminders and those using other technologies. However, there is growing evidence that reminders are not enough and patient engagement is vital. A recent [study](#) shows that use of a high-touch pharmacy patient engagement system made patients 2.57 times more likely to remain adherent with their medications. Promising results also were seen in two pilots at Duke University of a patient-facing application that engages patients about medication adherence through the use of questionnaires and availability of educational resources.

- **Addressing cost of prescriptions.**

The cost of prescriptions is a major cause of medication non-



compliance. According to a [survey](#) by CVS Caremark, 62% of retail pharmacists believe the high cost of drugs is the biggest reason why patients are noncompliant. Even raising copay amounts can unintentionally reduce medication adherence. Innovative pilots can be developed to create new medication payment structures (including free medications and patient assistance programs) that could improve compliance. The emergence of the Real-Time Benefit Inquiry could be helpful in addressing adherence by providing even more accurate information at the point of prescribing addressing which particular medications for a patient's condition would be a good fit with insurance coverage and the ability to pay out-of-pocket costs.

- **Analyzing data.**

Data analytics can be used to identify compliance issues and develop smart interventions. EHR data, supplemented by lifestyle and sociodemographic information, can be captured and analyzed to predict compliance problems. Integrating pharmacy claims data into the mix also can provide valuable insights. Population health vendors already are making investments in assessing medication adherence and risk factors in their core risk analytics applications (such as risk stratification dashboards) for providers' care teams.

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- **Educating patients and providers.**

Lack of health literacy is another cause of medication non-compliance. As a result, patients need to be educated about their disease, the benefits of the medicine being prescribed and instructions for properly taking it. This feeds into improved compliance. Similarly, providers need to be educated about the impacts of noncompliance and how EHRs and other technologies can help identify patients at risk as well as those who have become noncompliant.

- **Leveraging innovative partnerships.**

Health care organizations are developing numerous strategies and tools to help patients adhere with their medication regimens. An example is the eHealth Initiative's Electronic Medication Adherence Collaborative, which is aimed at helping to identify how information technology and data analytics can be used to improve medication adherence. It will include a consumer-oriented approach to understand the behavioral and economic factors that influence patient behaviors and preferences.

- **Mining the research.**

There is a growing amount of literature concerning medication adherence, yet, to our knowledge, no meta-analysis has been done. Such analyses could better inform policies and practices, as well as help connect researchers to policy makers.

Bringing it all together. Medication adherence is an area of focus for Point-of-Care Partners, building on our expertise in electronic prescribing and eMedication management. Please let me know if I can provide you with more information. Contact me at [tonys@pocp.com](mailto:tonys@pocp.com).



# 2

## Part 2: The Impact of New, Nonproprietary Naming Convention for Biologics and Biosimilars: 7 Key Findings



By **Pooja Babbar**, Senior Consultant

**W**hat are the costs and burden associated with implementing the proposed, nonproprietary naming convention for biologics and biosimilars from the Food and Drug Administration (FDA)? It depends. All stakeholders will have to make some modifications to comply. However, the extent of the new naming convention is stakeholder specific and will also depend on the total number of drugs that will be involved. Those are among the findings of an in-depth study on the topic by Point-of-Care Partners (POCP), which undertook the project to better understand the range of stakeholders' concerns and potential impacts.

### How the naming convention would work.

Requirements for the changeover were spelled out in the FDA's January 2017 [guidance](#). Going forward, all biologics and biosimilars will have a unique, non-proprietary name that is a combination of the drug's core name and a distinguishing suffix that is devoid of meaning and composed of four lowercase letters (e.g., infliximab-dyyb). These requirements apply to both newly licensed biologics and biosimilars, and will also be applied retrospectively to biologics already on the market.

According to the FDA, the new naming convention seeks to: 1) help prevent inadvertent substitution (which could lead to medication errors) of biological products that are not determined to be interchangeable by the FDA; and 2) support safety monitoring of all biological products after they are on the market by making it easier to accurately track their usage in all care settings (including outpatient, hospital and pharmacies) as well as trace adverse events back to the manufacturer and batch.

### A work in progress.

As expected, there are still many details to be worked out. For example, there is no final guidance on the format of the naming and suffix for interchangeable biosimilars as the FDA is still trying to determine if it's best for the suffix of an interchangeable product to be "related" to its originator product or unique for pharmacovigilance purposes. In addition, retrospective name change of existing products is not ready for implementation because approval would be needed from the Office of Management and Budget, which routinely reviews the burden impacts of significant proposed regulatory guidance as required under the Paperwork Reduction Act. If and when it is implemented, it will be done with significant lead time. Also, as currently written, it will allow the manufacturer or holder of a Biologics License Application (BLA) to propose a suffix rather than having one randomly assigned.

In the future, the FDA wants to make sure name changes are communicated clearly to health information technology (health IT) vendors. Structured product label files will now include additional indicators (for example, a field for the biological drug substance name with suffix and beginning and ending dates of name) to help vendors link the old names and files together. This could help mitigate implementation concerns of drug data compendia vendors.

### POCP's study.

To better understand the impact of the FDA's new naming convention, POCP conducted in-depth interviews with key staff from drug data compendia, vendors and users of electronic



health records (EHRs) and computerized physician order entry (CPOE) systems, pharmacists and a pharmacy system vendor. Findings show implementation of the guidance will, indeed, impact the industry, especially as it relates to existing biologics on the market, and, in most cases, stakeholders will be required to make some coding changes, system retrofits and other adaptations to accommodate the change. However, the extent of the impact is stakeholder specific and will also depend on the total number of drugs impacted by the guidance.

## Study findings.

Here are seven key findings reflecting specific stakeholders' concerns and impacts.

### 1. Implementation concerns.

While all stakeholders appreciate the FDA's efforts, many are concerned about the costs, burden and unintended consequences of implementation. For example, the National Council for Prescription Drug Programs believes the "FDA's new naming convention arises from an incomplete awareness of the comprehensive electronic programming, which underlies how drugs are prescribed and dispensed." This infrastructure — largely due to federal efforts over nearly a decade to promote health IT — is now pervasive. As a result, the changeover in systems by the new naming convention could be costly and burdensome to implement. Some also fear unintended consequences. One of the most significant examples is potential payment delays created while all public and private payers retrofit their systems and formularies to accommodate the renaming of every biological drug, including those that have been marketed for years under a different nonproprietary name.

### 2. Changes occur in today's market and are handled successfully.

POCP's research shows that implementation of the guidance might not be as burdensome or costly as some stakeholders had suggested. One reason is that the industry is used to making numerous changes in their systems related to the drugs used today. For example, changes often occur to National Drug Code (NDC) numbers, product descriptions and therapeutic classifications, not to mention product name changes. In our discussions with EHR vendors and pharmacists, all stated that they

successfully manage these types of changes today with minimal impact on day-to-day operations. There are established methods for addressing these market changes. Therefore, changes to address the new naming convention for biologics and biosimilars are nothing new in that respect. However, many of the concerns voiced by industry relate to the total number of products that might be impacted by the new requirements. DailyMed lists roughly 15,000 NDCs. The sheer volume of potential changes is a significant concern.

### 3. Unclear scope.

At this point, it is unclear whether the FDA's guidance applies to every United States (US) product with an approved BLA or only to those on the Center for Drug Evaluation and Research (CDER) list of licensed biological products. To be sure, the answer to this will directly impact costs and burden. If the final rule applies solely to the those on the CDER list, it would affect name changes for only 131 products representing approximately 900 NDCs, as opposed to thousands that were referenced in many of the comments and concerns voiced to the FDA during the comment period on the guidance. The total number of NDCs affected could be much less if a name change applies only to products that have proposed multiple sources.

### 4. Impacts on drug compendia.

The new guidance will have the greatest impact on drug compendia as they will have the most work to retrofit systems. These companies believe the new naming requirement is unnecessary because their current algorithms and processes already accomplish what the FDA hopes to achieve, namely preventing inadvertent substitution, tracking biologics through the entire system and tracing adverse events back to the manufacturer. Compendia currently follow a specific process for creating the files and databases used by EHRs, hospital information systems and pharmacy system vendors. As part of it, compendia vendors group similar products using specific identifiers, including International Nonproprietary Name (INN), strength and dosage form. This process of grouping drugs will likely be impacted by the guidance. For example, compendia will need to recreate links between old and new generic names for all products, update the data they provide to clients and potentially introduce different files and processes for biologics. This could impact



POCP's research shows that implementation of the guidance might not be as burdensome or costly as some stakeholders had suggested.

their clients as there are many variations in how their files are currently implemented at various vendors and institutions. For the compendia themselves, [current research](#) estimates that the coding changes necessary to accommodate the addition of an FDA-approved suffix could take up to 50 hours per product. However, if compendia can handle these products in a similar manner as they do today, there will be less of an impact on both their own operations and to their client base.

The drug database companies believe there is no reason to change this current process and the introduction of this new naming convention will simply cause unneeded confusion among prescribers. Some went so far as to argue that using suffixes will lead to higher prescribing of source medications, thus defeating the cost-saving purpose of introducing biosimilars. Furthermore, compendia executives with whom we've spoken argue that the proposed naming convention will not help improve the ability to track and trace an adverse event, which they believe is better handled through existing processes. These include capturing and storing the accurate dispensed medication data in all of the systems involved with the medication prescribing and dispensing process. At the end of the day, the costs and impacts to compendia will be based on the total volume of NDCs impacted, including any potential changes needed to regroup and/or implement indicators of the biosimilar and biologic reference product relationships.

## 5. Impacts on EHRs.

According to the ambulatory and acute EHR vendors and their users with whom we've spoken, name changes for biologics and biosimilars would have minimal to no impact on their systems and operations. Today, most EHR vendors will take the file(s) that compendia provide, run a quality check and prepare it for loading into their system. Updates to the drug file appear in the EHR anywhere between 2 weeks and 6 months, depending on the configuration of the EHR and the timing of when a practice updates its database. Because NDC and name changes happen today, most believe there would be limited impact in terms of cost and resources to handle these changes. That said, EHR vendors should pay attention to the FDA's guidance and any communications from the drug compendia related to this topic. Due to the large number of NDCs that may be impacted by the FDA's guidance, for example, it would be prudent for EHR vendors to take time to review the files in more detail. Also, depending on how the drug compendia choose to handle the changes, additional programming may be needed for an EHR vendor to link old and new NDCs, and the biologics may end up being provided in a separate file for the EHR vendor to download. If this route is taken by compendia vendors, the impact to EHRs would be greater than they are anticipating today.

Another area identified that may impact EHRs is the messaging to the provider when an electronic refill message is sent from

the pharmacy to the provider. If a name change occurs and the linkage between the old and new name has not been made in the drug file, it may appear to the provider that the drug is no longer available for prescribing when, in fact, it is simply a name change for the drug. At the end of the day, EHR vendors should focus on taking extra time to thoroughly review changes to compendia files and review the links to ensure proper messages are being provided to the prescriber regarding the name change. This is highly recommended as a best practice, which is better implemented sooner rather than later.

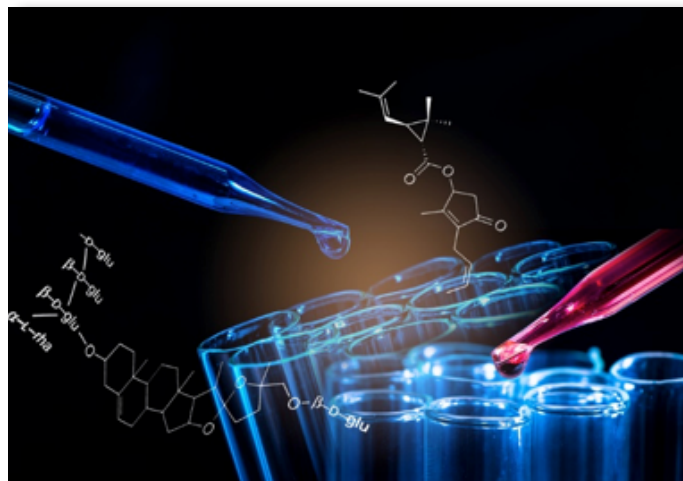
## 6. Impacts on pharmacy (retail, mail, specialty, long-term care).

The pharmacy stakeholders with whom we've spoken don't anticipate that a name change alone for biologics and biosimilars will have substantial impact on pharmacy operations. Like EHR vendors, pharmacy system vendors use the compendia files, which link products into appropriate groups and thus can be used to identify similar products and provide a guide for substitution. Additional time and resources will likely be needed to quality check the files due to the potentially large number of changes.

The greater impact to the pharmacy staff and systems is related to the back-end processes, as opposed to the front-end dispensing of the drug. The FDA guidance addresses name change only and does not indicate if an NDC change must occur along with the name change. If an NDC change occurs along with a name change, billing and inventory management may be impacted during the transition period from old to new NDC. It is likely that there will be a transition period in which a pharmacy would have inventory with both the old and new NDC numbers. Any billing of product during that time would have to be carefully reviewed to ensure that the pharmacy is billing for the NDC number that was dispensed. There would be no programming changes required related to this issue because these are primarily process and operations changes to ensure that the name and/or NDC changes are clearly communicated to staff to ensure the correct billing of existing inventory during the transition period.

## 7. Impacts on hospitals, clinics, infusion centers and related facilities.

For the most part, a name change alone will have limited impact



on existing ambulatory and hospital electronic prescribing systems for the same reasons we have stated above: changes to product names and NDCs occur today and are handled by all stakeholders. However, discussions with users of CPOE systems in hospitals revealed that their main concern was related to how ancillary systems would need to be integrated with their EHR or CPOE system, such as lab and radiology software integrations. In reality, the vendors and facilities have no control over what changes may be needed in the application program interfaces (APIs) that are used by add-on products to the primary EHR or CPOE systems. Facilities could experience a bigger impact if a name or NDC change requires significant alterations to interfaces or if updates are needed to APIs.

## Bringing it all together.

Through our research and interviews with stakeholder groups, we've determined that the guidance provided by the FDA concerning biologic and biosimilar naming will have an impact on all stakeholders in the industry. However, the extent of that impact depends on the volume of products involved as well as the extent of the change (i.e., name only or name and NDC number). The consensus among industry stakeholders with which we've spoken was that the guidance will likely pertain to the smaller list of drugs — those on the CDER list versus all US products with an approved BLA. POCB has been keeping on top of this issue. Let us know if you would like more information. We'd be happy to do a deeper dive for you on the market impacts of the FDA's new guidance and our research. Contact me at [poojah.babbarah@pocp.com](mailto:poojah.babbarah@pocp.com).

# 3 Part 3: ONC to Significantly Scale Back EHR Certification and Enforcement



By **Michael Burger**, Practice Lead, EHRs and EDI

Stakeholders of all kinds were surprised when the government proposed it will significantly scale back certification testing requirements for electronic health records (EHRs) as well as lessen the burden of enforcement for both EHR vendors and ONC Authorized Certification Bodies (ONC-ACBs). The out-of-the-blue announcement came in a September 21 [blog](#) post from the Office of the National Coordinator for Health Information Technology (ONC).

## How the changes will work.

Under the proposal, vendors will be able to “self-declare” that their products meet 30 of 55 certification categories. These self-declared criteria are “functionality based” and cover such things as medication and problem lists, computerized physician order entry, patient-specific education resources, and drug formulary and preferred drug list checks. Functionalities no longer needing testing are included in a detailed list of certification testing specifications on ONC’s 2015 certification testing [web page](#).

Vendors must, however, undergo certification testing to demonstrate compliance with the remaining 25 criteria. ONC says that nearly all functionalities still requiring testing are related to interoperability, which is one of the agency’s main areas of focus.

On the enforcement side, ONC-ACBs will have discretion to prioritize surveillance based on complaints received rather than the current requirement to conduct randomized surveillance on a tiny percentage of the health information technology certifications they issue. This modification moves surveillance from a proactive to reactive mode. Reported problems about EHRs or



certification standards will be reviewed and investigated by testing authorities.

## Impacts.

Many stakeholders are still digesting what the changes will mean. Here’s what we know so far:

### • ONC.

The proposed changes will lighten workload at ONC, which is likely to be facing significant budget cuts in fiscal year 2018. They will help ONC fulfill its requirements under the 21st Century Cures Act as well as align with the Trump administration’s overall desire to reduce regulatory burdens. We speculate the changes are related to implementation of ONC’s [five-year plan](#) to revamp its certification program, which was announced on August 3. ONC expects the plan will change the focus from

reliance on testing tools financed by “taxpayer dollars” to tools developed by the industry and provided free of charge.

- **Vendors.**

We believe the proposed changes are good news for vendors. They will create bandwidth, which will open the door for innovation. Vendors will be able to redirect time and resources spent on certifying basic functionalities to improving usability, creating new features and meeting demand for data sharing. New features to be considered might include prescription-related functions such as electronic prior authorization, biosimilars and automation of specialty pharmacy enrollment. The streamlined certification approach should allow vendors to bring more 2015 certified products into the marketplace, thus encouraging physicians and hospitals to stick with the meaningful use (MU) agenda.

A potential downside to the change from proactive to reactive compliance surveillance is vendors could be subjected to more claims from users claiming substandard functionality. Absent a broad certification process, compliance with the requirements will be subjective, based on each vendor’s interpretation and the interpretation of their customers.

- **Physicians.**

On one hand, the changes are important because they should increase the availability of EHRs meeting 2015 certification. This will help providers in meeting requirements for MU stage 3 and Advancing Care Information — an EHR-based scoring methodology for Medicare physician payment that is part of the Medicare Quality Payment Program, which was created to align with the requirements of the Medicare and CHIP Reauthorization Act.

On the other hand, physician advocacy groups are wary that the changes in certification and enforcement would have unintended consequences on patient care and directly affect EHR utilization. For example, some fear that less regulation will not necessarily result in more interoperable and usable EHRs. Concerns have been raised that there will not be enough vendor accountability around self-attestation, leaving physicians to identify compliance problems that might have been found through testing and resolved before the EHRs hit the market.

The proposed changes will lighten workload at ONC, which is likely to be facing significant budget cuts in fiscal year 2018.

We look forward to the industry stepping up to take advantage of the found bandwidth to continue to refine usability and innovate game-changing features. I am interested in your reactions. You can reach me at [michael.burger@pocp.com](mailto:michael.burger@pocp.com).

