SPRING 2019

NETWORK INSIDER

Cigna-HealthSpring news you can use

FLUOROQUINOLONE ANTIMICROBIALS

Are they worth the risks?

Over the past decade, the Food & Drug Administration (FDA) has issued numerous safety warnings associated with systemic fluoroquinolone antimicrobials. As additional evidence is discovered and side effects compound, it's becoming increasingly important to ensure fluoroquinolones are only administered to patients for treatment of serious bacterial infections in which benefits outweigh risks.

TIMELINE OF WARNINGS

July 8, 2008:[1] The FDA added a boxed warning, which is the FDA's highest warning, regarding the increased risk of tendinitis and tendon rupture. This risk is further increased in patients over age 60, with kidney, heart, or lung transplants, and with use of concomitant steroid therapy.

August 15, 2013:[2] The FDA highlighted a new warning for potentially irreversible peripheral neuropathy. This severe side effect can occur at any time during treatment with fluoroquinolones, often within a few days, and may be disabling.

May 12, 2016:[3] The FDA recommended restricting use of fluoroquinolones for certain uncomplicated infections when other treatment options are available. The serious risks generally outweigh the benefits for the following bacterial infections: acute sinusitis, acute bronchitis, and uncomplicated urinary tract infections. This recommendation was updated **July 26, 2016**[4] to a boxed warning regarding the risk of the disabling and potentially permanent side effects of tendons, muscles, joints, nerves, and central nervous system.

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FLUOROQUINOLONE ANTIMICROBIALS *CONTINUED*

July 10, 2018:[5] The FDA strengthened the current warnings in the prescribing information that fluoroquinolones may cause significant decreases in blood sugar and certain mental health side effects. Fluoroquinolone-induced hypoglycemia can be severe, potentially leading to coma and/or death. Hypoglycemia was found to occur most frequently in the elderly and those with diabetes taking an oral hypoglycemic medication or insulin. While the mental health side effects were previously described in the drug labels, the new changes made the side effects of attention disturbances, disorientation, agitation, nervousness, memory impairment, and delirium more prominent/evident and consistent across the fluoroquinolone class.

December 20, 2018:[6] The FDA released a strong warning for increased occurrence of rare but serious events of aortic ruptures. This was an update to a previous FDA announcement on May 10, 2017, after multiple recent studies demonstrated that the risk of an aortic aneurysm rupture was twice as high in patients taking fluoroquinolones. The FDA recommends that health care professionals avoid prescribing fluoroquinolones to patients with an aortic aneurysm or at high risk for an aortic aneurysm. High-risk patients include those with peripheral atherosclerotic vascular disease, hypertension, certain genetic conditions such as Marfan syndrome and Ehlers-Danlos syndrome, and elderly patients.

The FDA strongly encourages health care providers to prescribe fluoroquinolones to patients without risk factors for medication adverse effects, and for those in whom a bacterial infection is severe enough to warrant fluoroquinolones where other antimicrobial options would not be medically appropriate. When prescribing fluoroquinolones, patients should be advised of all potential adverse effects and instructed to seek medical attention for any symptoms potentially associated with side effects. Additionally, the FDA urges health care providers, as well as patients, to report side effects involving fluoroquinolones or other medications to the FDA MedWatch program. For more information or to subscribe to FDA MedWatch alerts, please visit www.fda.gov/Safety/MedWatch.

Marketed fluoroquinolones currently include: ciprofloxacin (Cipro®, Cipro® XR, Proquin® XR), gemifloxacin (Factive®), levofloxacin (Levaquin®), moxifloxacin (Avelox®), norfloxacin (Noroxin®), and ofloxacin (Floxin®).

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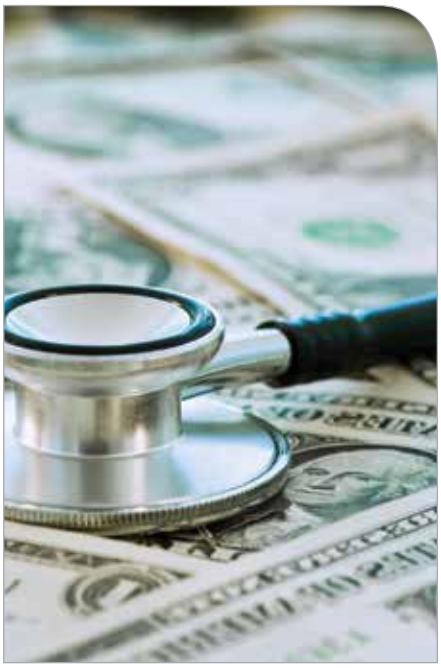
FLUOROQUINOLONE ANTIMICROBIALS *CONTINUED*

References

1. U.S. Food and Drug Administration (FDA): Information for Healthcare Professionals: Fluoroquinolone Antimicrobial Drugs Increased risk of Tendinitis and Tendon Rupture. U.S. Food and Drug Administration (FDA). Silver Spring, MD. 2008. Available from URL: http://wayback.archive-it.org/7993/20170112032310/http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm126085.htm. As accessed January 2019.
2. U.S. Food and Drug Administration (FDA): FDA Drug Safety Communication: FDA requires label changes to warn of risk for possibly permanent nerve damage from antibacterial fluoroquinolone drugs taken by mouth or by injection. U.S. Food and Drug Administration (FDA). Silver Spring, MD. 2013. Available from URL: http://wayback.archive-it.org/7993/20170112031629/http://www.fda.gov/Drugs/DrugSafety/ucm365050.htm. As accessed January 2019.
3. U.S. Food and Drug Administration (FDA): FDA Drug Safety Communication: FDA advises restricting fluoroquinolone antibiotic use for certain uncomplicated infections; warns about disabling side effects that can occur together. U.S. Food and Drug Administration (FDA). Silver Spring, MD. 2016. Available from URL: https://www.fda.gov/Drugs/DrugSafety/ucm500143.htm. As accessed January 2019.
4. U.S. Food and Drug Administration (FDA): FDA Drug Safety Communication: FDA updates warnings for oral and injectable fluoroquinolone antibiotics due to disabling side effects. U.S. Food and Drug Administration (FDA). Silver Spring, MD. 2016. Available from URL: https://www.fda.gov/Drugs/DrugSafety/ucm628753.htm. As accessed January 2019.
5. U.S. Food and Drug Administration (FDA): FDA Drug Safety Communication: FDA reinforces safety information about serious low blood sugar levels and mental health side effects with fluoroquinolone antibiotics; requires label changes. U.S. Food and Drug Administration (FDA). Silver Spring, MD. 2018. Available from URL: https://www.fda.gov/Drugs/DrugSafety/ucm611032.htm. As accessed January 2019.
6. U.S. Food and Drug Administration (FDA): FDA Drug Safety Communication: FDA warns about increased risk of ruptures or tears in the aorta blood vessel with fluoroquinolone antibiotics in certain patients. U.S. Food and Drug Administration (FDA). Silver Spring, MD. 2018. Available from URL: https://www.fda.gov/Drugs/DrugSafety/ucm628753.htm. As accessed January 2019.

WHAT DOES "PATIENT HOLD HARMLESS" MEAN?

When a patient cannot be held financially liable for charges



Participating providers are prohibited from balance-billing Cigna-HealthSpring patients, including, but not limited to:

- Situations involving nonpayment by Cigna-HealthSpring,
- Insolvency of Cigna-HealthSpring, or
- Cigna-HealthSpring's breach of its Agreement.

Covered services

Provider shall not bill, charge, collect a deposit from, seek compensation or reimbursement from, or have any recourse against patients or persons, other than Cigna-HealthSpring, acting on behalf of patients for Covered Services provided pursuant to the Participating Provider's Agreement.

The provider is not, however, prohibited from collecting copays, coinsurances or deductibles for covered services in accordance with the terms of the applicable patient's Benefit Plan, or for collecting payment when rendering non-covered services if the provider complies with the requirements of the non-covered services section of the Provider Manual.

Non-covered services

Providers may only collect fees from patients for non-covered services when the patient has been provided with a standardized written organization determination denial notice from Cigna-HealthSpring prior to the item or service being rendered to the patient, or if the patient's EOC clearly states the item or service is a non-covered service.

In circumstances where there is a question whether or not the plan will cover an item or service, patients have the right to request a determination prior to obtaining the service from provider. If coverage is denied, Cigna-HealthSpring provides the patient with a standardized written determination denial notice which states the specific reasons for the denial and informs the patient of his or her appeal rights. In absence of the appropriate Cigna-HealthSpring determination denial notice or a clear exclusion in the EOC, the patient must be held harmless (cannot be held financially liable for the charges).

When a provider knows or believes that a service or item is not covered under the patient's benefit, and the EOC does not explicitly state the item or service as non-covered, the provider must advise the patient to request a pre-service organization determination from Cigna-HealthSpring or the provider can request the organization determination on the patient's behalf before the provider moves forward with rendering the services, providing the item, or referring the patient to another provider for the non-covered item or service.

Providers may not issue any form or notice that advises the patient they will be responsible for the costs associated with non-covered services unless the patient has already received the appropriate pre-service organization determination denial notice from Cigna-HealthSpring, or the service or item is explicitly stated as a non-covered service in the EOC.

APPOINTMENT ACCESS AND AVAILABILITY STANDARDS

Review the checklist

Cigna-HealthSpring establishes standards for appointments to ensure patients have timely access to care. Please ensure that your office is following the standards below, which are all measured yearly by Cigna-HealthSpring.

Primary care access standards

Appointment type	Access standard
Urgent/emergent	Immediately
Non-urgent/non-emergent	Within one week
Routine and preventive	Within 30 business days
On-call response (after hours)	Within 30 minutes for emergency
Waiting time in office	30 minutes or less

Specialist access standards

Appointment type	Access standard
Urgent/emergent	Immediately
Non-urgent/non-emergent	Within one week
Elective	Within 30 days
High index of suspicion of malignancy	Less than seven days
Waiting time in office	30 minutes or less

Behavioral health access standards

Appointment type	Access standard
Emergency and non-life-threatening	Within six hours of the referral
Urgent/symptomatic	Within 48 hours of the referral
Routine	Within 10 business days of the referral*

After-hours access standards

All participating providers must return telephone calls related to medical issues. Emergency calls must be returned within 30 minutes of the receipt of the telephone call. Non-emergency calls should be returned within a 24-hour time period. A reliable 24 hours a day/7 days a week answering service with a beeper or paging system, and on-call coverage arranged with another participating provider of the same specialty is preferred.

*For detailed information on access standards, visit the online provider manual at https://www.cigna.com/medicare/health-care-providers/provider-manual/2019-provider-manual.

YOUR PRACTICE INFORMATION

How to update changes

The Centers for Medicare & Medicaid Services (CMS) requires the maintenance of accurate data in provider directories. Up-to-date provider information allows Cigna-HealthSpring to:

- Accurately generate provider directories.
- Process claims.
- Communicate with our network of providers.
- Help patients locate your practice information.

Providers must notify Cigna-HealthSpring in writing at least 30 days in advance (when possible) of changes, such as:

- Change in practice ownership or Federal Tax ID number.
- Practice name change.
- A change in practice address, phone or fax numbers.
- Change in practice office hours.
- New office site location.
- Primary Care Providers Only: If your practice is open or closed to new patients.
- When a provider joins or leaves the practice.

Next steps

- Update your profile in Council for Affordable Quality Healthcare, Inc. (CAQH) at https://proview.caqh.org/.
- For more information, contact your Network Operations Representative.

PATIENT GRIEVANCES

Overview

It's their right. Your Cigna-HealthSpring patients have the right to file a complaint, also referred to as a grievance, regarding any problems they observe or experience with the health plan. Situations for which a grievance may be filed include, but are not limited to:

- Complaints about services in an optional Supplementary Benefit package.
- Dissatisfaction with the office experience such as excessive wait times, physician behavior or demeanor, or inadequacy of facilities, such as wheelchair access.
- Involuntary disenrollment situations.
- Poor quality of care or services received.

It's our responsibility. Please ensure that your office staff treats patients with dignity, respect and fairness at all times.

If your patients need help with communication, such as help from a language interpreter, direct them to call Cigna-HealthSpring Customer Service. Customer Service Representatives can also help customers file complaints. The phone number is **1-800-668-3813**.

STATIN USE IN PERSONS WITH DIABETES

Information about this important triple-weighted measure

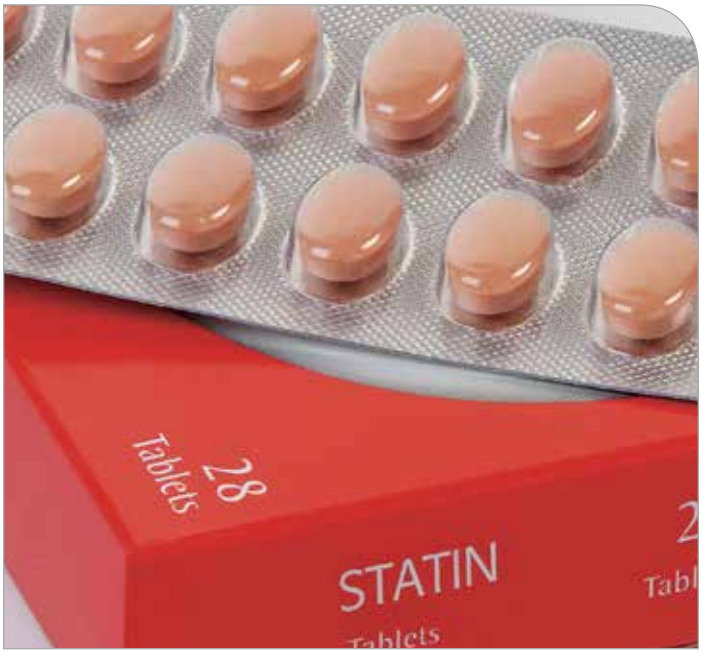
SUPD measure definition: The percentage of Medicare Part D beneficiaries age 40–75 who received **at least two diabetes medication fills** and also received a statin medication during the measurement period.

- **Measurement period:** The report measurement period represents a single contract year (Jan. 1–Dec. 31).
- **Eligibility criteria:** Active enrollment for at least one month of the contract year.
- **Exclusions:** Hospice or End Stage Renal Disease (ESRD).
- **Denominator:** Number of member-years.

Cigna-HealthSpring teams or designated vendors may perform outreach to the prescriber or patient when gaps for this measure persist. Patients are included in outreach when they:

- Are between age 40–75.
- Take two or more diabetic medications.
- Have zero pharmacy claims for a statin medication of any type within the measurement year.

In 2013, the ACC and AHA published guidelines identifying "Four Major Statin Benefit Groups" (2013 ACC/AHA Guideline on Treatment of Blood Cholesterol to Reduce Atherosclerotic Cardiovascular Risk in Adults: A Report of the American College of Cardiology/ American Heart Association Task Force on Practice Guidelines). One of the four groups that should be on statin therapy is "Individuals … [with] diabetes age 40 to 75 years with LDL 70 to 189 mg/dL and without clinical ASCVD."



This group includes patients with normal LDL levels and without any history of heart disease, stroke, or peripheral vascular disease. It is a Strong (Grade A) Recommendation = There is high certainty based on evidence that the net benefit is substantial.

Why did the ACC/AHA identify this group as one of the most likely to benefit from statin therapy for primary prevention of ASCVD? (American Diabetes Association. Standards of Medical Care in Diabetes – December 2016) "… These individuals are at substantially increased lifetime risk for ASCVD events and death [the same risk as an individual who already had a cardiovascular event]. Moreover, individuals with diabetes experience greater morbidity and worse survival following the onset of [CVD]." In adults with diabetes without CVD, moderate-dose statin therapy reduced the relative risk for CVD events by 27% per 38.7 mg/dL of LDL reduction.

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STATIN USE IN PERSONS WITH DIABETES *CONTINUED*

A 2018 Meta-analysis of Cholesterol Treatment Trialists Collaboration (CTTC) and Medline data published by JAMA found that there is continued risk reduction at sub-70 mg/dL levels without safety concerns.
(Efficacy and Safety of Further Lowering of Low-Density Lipoprotein Cholesterol in Patients Starting With Very Low Levels – A Meta-analysis. JAMA Cardiol. 2018;3(9):823–828. Published online August 1, 2018.)

"There is consistent relative risk reduction in major vascular events per change in LDL-C in patient populations starting as low as a median of 1.6 mmol/L (63 mg/dL) and achieving levels as low as a median of 0.5 mmol/L (21 mg/dL), with no observed offsetting adverse effects.

"These data suggest further lowering of LDL-C beyond the lowest current targets would further reduce cardiovascular risk."

Barriers and Solutions
Most common reasons for discontinuation of statins include muscle side effects (60%), cost (16%) and perceived lack of efficacy (13%).
(Wei MY, Ito MK, Cohen JD, Brinton EA, Jacobson TA. Predictors of statin adherence, switching, and discontinuation in the USAGE survey: understanding the use of statins in America and gaps in patient education. J Clin Lipidol 2013;7:472–483.)

1. **Patient has documented "adverse effect" to statin(s)**
   Note that more than half of patients that stopped a statin due to a statin-related event were successfully restarted with a statin. (Zhang H, Plutzky J, Skentzos S, Morrison F, Mar P, Shubina M, et al. Discontinuation of statins in routine care settings: a cohort study. Ann Intern Med 2013;158:526–534.)

   Was this documented following therapy from current provider or is this historical information provided by the patient? Confirm the nature of the adverse effect. What was the severity of the "adverse effect"?

   - Minor muscle pain, mild elevations in liver enzymes, mild elevation in blood sugar. Consider re-challenge with lower-dose or lower-intensity statin.
   - Rhabdomyolysis (leading to severe muscle pain, liver damage, kidney failure) or other significant adverse events. Avoid using statins as risks likely outweigh the benefits.

   Was the patient taking medications or eating grapefruit (known to interact with statins)? Common examples include: amiodarone, gemfibrozil, protease inhibitors, some antibiotics or antifungals, some immunosuppressants.

   - Is the offending medication or food still being used? If so, can it be discontinued or avoided? If no longer using, can the patient be re-challenged with a statin?

2. **Patient already has LDL <70 mg/dL and physician has concerns about prescribing a statin**
   Research shows further lowering of LDL-C beyond the lowest current targets would further reduce cardiovascular risk without offsetting adverse effects.

   Review supportive evidence from 2018 JAMA article referenced on page 1.

3. **A statin medication was prescribed, but the patient still appears as having a gap for SUPD**
   Note that the gap will only be closed if there

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STATIN USE IN PERSONS WITH DIABETES *CONTINUED*

is a paid pharmacy claim via the patient's insurance within the measurement year.

Did the patient fail to pick up the medication from the pharmacy?

- If so, why did this happen? Concerns about side effects, too expensive, etc.? Work with the provider to discuss side-effect concerns with patient (and possibility of a lower-dose or lower-intensity statin) or select an alternative statin available for a lower cost.
- Is the patient paying "out of pocket," using the VA, manufacturer coupons, cash, etc. rather than using his or her insurance coverage?
- Confirm for patient if option exists to get statin cheaper through insurance coverage (consider reviewing patient benefits for 90-day supply incentives and confirm member uses a preferred pharmacy).

4. **Patient doesn't believe the statin is making a difference (don't "feel" any different)**
Educate the patient on the mechanism of statins and how they help prevent cardiovascular events. Explain benefits vs. risks.
   - Review supportive evidence from ACC/AHA and ADA Guidelines.

CARE COORDINATION FOR DUAL ELIGIBLE PATIENTS

Plus information about the QMB and QMB Plus programs

Many of your patients may have Cigna-HealthSpring as their primary insurance payer and Medicaid as their secondary payer. You must coordinate the benefits of "dual eligible" Cigna-HealthSpring patients by determining whether the patient should be billed for the deductibles, copays or coinsurance associated with their benefit plan.

Providers will accept Cigna-HealthSpring's payment in full and not seek additional payment from the state or dual eligible customers.

Medicaid eligibility can be obtained by using the Medicaid telephone Eligibility Verification System. If you do not have access to the system, please contact your State Medicaid provider.

Important information about QMB and QMB Plus

Providers may not bill a Qualified Medicare Beneficiary (QMB) or QMB Plus for Cigna-HealthSpring copays, coinsurances and/or deductibles. Each state varies in their decision to cover the cost-share for populations beyond QMB and QMB Plus.

CMS PRECLUSION LIST

Quickfire Q&A

As of January 1, 2019, the Centers for Medicare & Medicaid Services (CMS) started publishing a monthly Preclusion List.

Q: What is the CMS Preclusion List?

A: A list of providers and prescribers precluded from receiving payment for Medicare Advantage (MA) items and services or Part D drugs furnished or prescribed to Medicare beneficiaries.

Q: What is its impact?

A: Part D sponsors must reject pharmacy claims (or deny a beneficiary request for reimbursement) for a Part D drug that is prescribed by an individual on the Preclusion List. MA plans must deny payment for a health care item or service furnished by an individual or entity on the Preclusion List.

Q: Who is on the list?

A: Individuals or entities who:

- Are currently revoked from Medicare, are under an active re-enrollment bar, and CMS has determined that the underlying conduct that led to the revocation is detrimental to the best interests of the Medicare program.

  CMS could have revoked the individual or entity to the extent applicable if they had been enrolled in Medicare, and CMS determines that the underlying conduct that would have led to the revocation is detrimental to the best interests of the Medicare Program.

Q: Are providers or entities notified when they are placed on the Preclusion List?

A: Yes. In advance of inclusion on the list, CMS sends an email and letter to the:

- Provider Enrollment Chain and Ownership System (PECOS) address, or
- National Plan and Provider Enumeration System (NPPES) mailing address.

  The letter includes the reason for the preclusion, the effective date of the preclusion, and applicable rights to appeal.

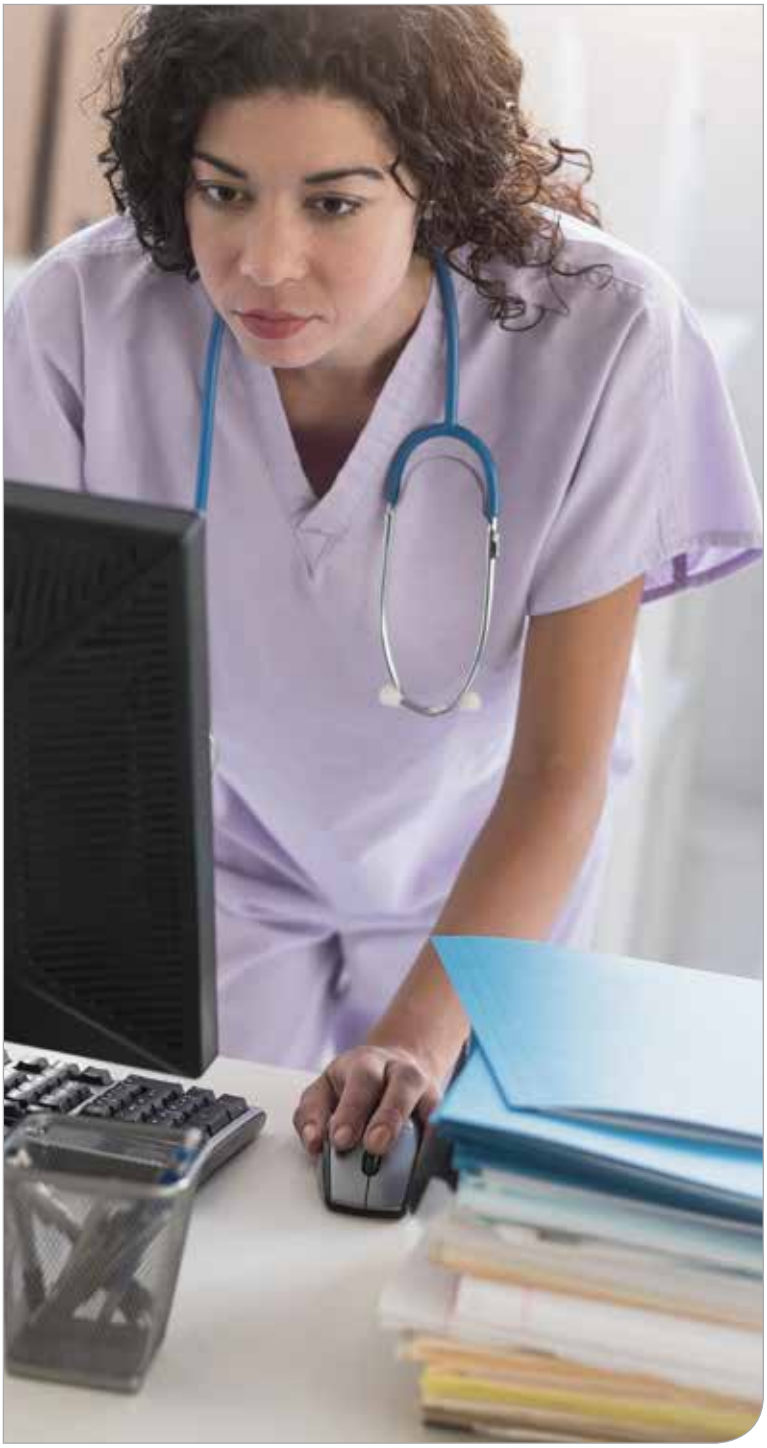
For more information, visit www.cms.gov/Medicare/Provider-Enrollment-and-Certification/MedicareProviderSupEnroll/PreclusionList.html.

REDUCE ADMINISTRATIVE BURDEN ON YOUR PRACTICE AND PATIENTS WITH CAQH PROVIEW

1.4 million health care providers use Council for Affordable Quality Healthcare (CAQH) ProView as their one-stop shop to streamline administrative paperwork for multiple insurance plans. CAQH ProView is fully electronic and was developed to save your staff and you the time it takes to complete the lengthy paper forms needed for each health care organization with which you are affiliated, and it's at no charge to you.

- Self-report and electronically store professional information in one user-friendly online data source.
- Directly upload credentialing documents to improve the accuracy and timeliness of applications.
- Share information common to multiple practice locations among providers in that practice.
- Maintain control of professional information with security features and authorize specified organizations to receive it.

To sign up or learn more about CAQH Proview, go to https://www.caqh.org/solutions/caqh-proview.



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