

WILLIAMS MULLEN ON CALL



INSIDE

FCA Settlement Alert: Physician Compliance with CMS' 60-Day Overpayment Rule.....2

Legislative Efforts to Improve Due Process for the Medicaid Audit Appeal Process4

HIPAA Check: Do You Know What to Do if a Breach Happens to You?5

North Carolina State Health Coordinating Council Votes on Proposed 2018 State Medical Facilities Plan.....7

Senior Housing Transactions in 20178

The Opioid Crisis: An interview with Mandy K. Cohen, MD, MPH, Secretary of the N.C. Department of Health and Human Services 10

Physician Practice Payment Reimbursement Reform and Strategies: An interview with Steve McCoy, Vice President/General Counsel, Patient First.....12

Welcome to the third edition of *Williams Mullen On Call*. In this edition, we are pleased to provide two very timely interviews. The first interview is with Mandy K. Cohen, MD, MPH, Secretary of the North Carolina Department of Health and Human Services, discussing strategies that North Carolina is implementing to address the opioid crisis. The second interview is with Steve McCoy, Patient First's Vice President/General Counsel, focusing on evolving physician payment reform and strategies. Each of those health industry leaders shares insights which we trust you will find informative and thought provoking.

Among the articles included in this edition are: Jeremy Ball's discussion of recent case law under the CMS 60-day overpayment rule, Matt Cobb's status report on the ongoing discussions with the Virginia Department of Medical Assistance Services on due process concerns with its audit appeal process, Kelsey Miller's practical tips on provider responses to a HIPAA breach, Joy Heath's overview of North Carolina's proposed 2018 State Medical Facilities Plan and Jim Bailey's presentation on 2017 senior housing transactions.

We invite you to let us know your thoughts about this publication and to identify any additional issues of interest to you. Thank you for joining us for this edition, and we look forward to presenting you with what we hope you will find to be insightful and practical information for years to come.



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FCA SETTLEMENT ALERT: PHYSICIAN COMPLIANCE WITH CMS' 60-DAY OVERPAYMENT RULE

By Jeremy A. Ball

On October 13, 2017, the U.S. Attorney's Office for the Middle District of Florida announced a settlement for over \$440,000 with First Coast Cardiovascular Institute, P.A. ("First Coast"), a large cardiovascular physician practice based in Jacksonville, Florida. The settlement arose out of a lawsuit filed by a former employee of First Coast under the False Claims Act (FCA), a federal law that creates civil liability for submitting false or fraudulent claims to the federal government. While Department of Justice settlements with physician practice groups are not unusual, this settlement is noteworthy for at least a couple of reasons.

First, the alleged liability of First Coast arose out of its failure to timely refund overpayments received from multiple government health care programs, including Medicare, Medicaid, TRICARE, and the Veterans' health program. In other words, First Coast did not submit claims that were false or fraudulent in the typical sense, meaning, for example, that the services were not rendered, were not medically necessary, or were intentionally miscoded or up-coded. Rather, First Coast had allegedly accrued credit balances owing to federal health care programs because of fairly common billing irregularities. According to the

complaint filed in the suit, these irregularities occurred when government health programs were inadvertently double-billed, when the practice failed to coordinate bills among multiple insurers, when patients were improperly required to pay upfront, or when adjustments to charges were made after receipt of payment. While none of these irregularities, by itself, amounts to fraud, the lawsuit alleged that First Coast's failure to refund the money timely nonetheless violated the FCA.

The situation described above is often referred to as a "reverse false claim," and it does indeed implicate the FCA. In addition to prohibiting the submission of false or fraudulent claims, the FCA is also violated when a person "knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the Government." 31 U.S.C. § 3729(a)(1)(G). An "obligation," as that term is used in the statute, includes the duty to refund an overpayment of funds received from a federal health care program. See 31 U.S.C. § 3729(b)(3). Thus, if a medical practice is aware that it has received an overpayment, but nevertheless "knowingly conceals" or "knowingly and improperly avoids or decreases" its obligation to refund the money to the government, then it has

potentially violated the FCA. This was the theory upon which the government pursued its case against First Coast.

Although brought in the name of the United States and the State of Florida, the lawsuit against First Coast was filed by a former employee, Douglas Malie, who served as the practice's Executive Director. As alleged in the complaint, Mr. Malie engaged in a concerted effort beginning in May 2015 and continuing through at least June 2016 to inform and educate First Coast's management about the practice's large credit balance, which at the time exceeded one million dollars. Mr. Malie's efforts began with a seemingly basic recommendation to First Coast's management that it begin making efforts to repay the money, and ultimately ended with Mr. Malie issuing a blunt warning to management that failure to repay the credit balance owing to the government within 60 days could result in damages and fines under the FCA. First Coast allegedly took no action to refund the overpayments, which prompted Mr. Malie to file suit in August 2016.

The 60-day time period for refunding government overpayments, as referenced in Mr. Malie's complaint, is not

technically part of the FCA. Rather, the Affordable Care Act, which became effective in 2010, included amendments to Medicare and Medicaid program integrity rules expressly requiring providers to refund overpayments within 60 days. That law includes the following key requirements: (1) overpayments made by the Medicare or Medicaid programs must be refunded to the government within 60 days of being “identified,” or the date any corresponding cost report is due; (2) along with the overpayment refund, the person must provide a written explanation of the reason for the overpayment; and (3) any overpayment retained after the deadline for reporting and returning the overpayment is automatically defined as an “obligation” under the FCA. 42 U.S.C. § 1320a-7k(d). Thus, if a health care provider retains an overpayment from Medicare or Medicaid for more than 60 days after identifying the overpayment, as First Coast did, it is at immediate risk of facing a suit under the FCA.[1]

While many FCA cases drag out for years, the suit against First Coast was resolved in the relatively short period of only 14 months. For First Coast, however, that resolution came at a steep cost. According to the government press release, the total amount of the government overpayment received by First Coast was \$175,000,[2] while the settlement amount was over \$440,000, or more than 2.5



times the actual overpayment. It is also safe to assume that First Coast paid its own attorney’s fees, which were likely significant given the involvement of both the U.S. Attorney’s Office and the Attorney General for the State of Florida. Finally, Mr. Malie received roughly \$90,000 of the settlement proceeds as a successful whistleblower.

There are three key lessons that may be learned from the First Coast settlement:

1. Employee reports of an overpayment must be taken seriously. Providers have an affirmative obligation to diligently investigate suspected overpayments.
2. The legal requirement to refund Medicare and Medicaid overpayments has teeth and will be enforced by the Department of Justice in support of a private whistleblower, even when the amount of the overpayment is modest.

3. Liability under the FCA is not limited to instances of actual misrepresentation or fraud, but may also arise out of a failure to refund an otherwise innocent overpayment within 60 days of its identification.

In February 2016, the Department of Health and Human Services promulgated detailed regulations implementing the requirement that providers report and refund overpayments within 60 days. The details of those regulations are beyond the scope of this article. However, if you have questions about how to respond to a suspected or known overpayment from a federal health care program, Williams Mullen’s Health Care Team can help. I can be reached at jball@williamsmullen.com or 804.420.6406.

[1] Under CMS’ 60-day rule, an overpayment has been “identified” when a “person has, or should have through the exercise of reasonable diligence, determined that the person has received an overpayment and quantified the amount of the overpayment.” 42 C.F.R. § 401.305. “Reasonable diligence,” in this context, includes “both proactive compliance activities conducted in good faith by qualified individuals to monitor for the receipt of overpayments and investigations conducted in good faith and in a timely manner by qualified individuals in response to obtaining credible information of a potential overpayment.” 81 Fed Reg 7654, 7661 (Feb. 12, 2016). CMS believes that “reasonable diligence” requires a provider to complete its internal investigation of a potential overpayment within six months, except in extraordinary circumstances. *Id.* at 7662.

[2] Publicly available documents do not explain why the amount of the government overpayment was only \$175,000, while First Coast’s credit balance, as alleged in the complaint, exceeded \$1,000,000. We might guess that the \$1,000,000 credit balance included amounts owing that were unrelated to federal health care programs or that were refunded by First Coast prior to initiation of the litigation.

LEGISLATIVE EFFORTS TO IMPROVE DUE PROCESS FOR THE MEDICAID AUDIT APPEAL PROCESS

By *Matthew M. Cobb*

Responding to concerns raised by members of its Health Law Section, the Virginia Bar Association pursued budget language during the 2017 legislative session to address due process concerns with the manner in which the Department of Medical Assistance Services (DMAS) conducts its provider audit appeal process. The concerns arose from DMAS' application of recent Court of Appeals decisions to impose strict application of documentation requirements. This has resulted in numerous cases where DMAS sought full retractions for services clearly necessary, authorized and rendered, but where minor or technical documentation errors existed.

The General Assembly enacted budget language during its 2017 legislative session requiring DMAS to convene a workgroup with members of the Virginia Bar Association and provider groups to address these concerns by developing a plan to address non-material breaches of the provider agreement such as those minor documentation errors. The budget language called for:

The Department of Medical Assistance Services shall convene a workgroup with representatives from the

provider community, and the legal community, and the Office of Attorney General to develop a plan to avoid or adjust retractions for non-material breaches of the Provider Participation Agreement when the provider has substantially complied with the Provider Participation Agreement. The plan shall include an assessment of any administrative financial impact that implementation of such plan would have on the department and an analysis of any implications for the department's efforts to combat fraud, waste, and abuse. The workgroup shall report on the status of this plan to the Chairmen of the House appropriations and Senate Finance Committees no later than December 1, 2017.

The workgroup has met three times to discuss Medicaid appeals. While DMAS and provider representatives do not agree on whether a non-material breach and substantial compliance with the provider agreement should be allowable defenses, the workgroup has made progress on several issues.

For example, DMAS and the provider members of the workgroup are discussing changes to the

audit appeal process to permit settlements of audit claims to occur earlier, during the informal appeals process, which will reduce the time and expense providers face in some appeals. In addition, DMAS is considering reducing the review period during an audit from 15 months of claims to 12 months. The workgroup is also discussing ways to improve the flow of information between DMAS and the provider before, during and after the audit process.

The workgroup will report its effort and recommendations to the General Assembly on December 1, 2017. Williams Mullen will provide an update on the final outcome of the workgroup's efforts.

HIPAA CHECK: DO YOU KNOW WHAT TO DO IF A BREACH HAPPENS TO YOU?

By Kelsey S. Miller

Breaches happen. They happen to major health systems, and they happen to solo practitioners. They happen to health plans, and they happen to health information technology vendors. In our technology-reliant world, it would be easy to point fingers at the proliferation of our online lives as the problem. However, most breaches still have a decidedly “low-tech” component: human error. Even with the best security and best workforce training, breaches will occur, and when they collide with a highly-regulated industry such as health care, an old statute with new bite plays a significant role in how entities respond: the Health Insurance Portability and Accountability Act of 1996 (HIPAA).[1]

HIPAA and its implementing regulations dictate what health care providers, health plans, and health care clearinghouses can do with their “protected health information,” or “PHI,” and what measures these “covered entities” must put in place to enhance the security of their PHI.[2] The HIPAA rules also describe how to

know and what to do if you have experienced a “breach.”[3]

HOW DO YOU KNOW IF YOU HAVE A BREACH?

You have a set of facts that might indicate data compromise – an errant email, mysterious log-in activity to your electronic health



record or a lost or stolen laptop. How do you know if you also have a breach? HIPAA defines “breach” as any unpermitted use or disclosure of unsecured PHI, subject to a few narrow exceptions. Notification obligations are triggered unless a covered entity has determined, through a risk assessment, that there is a “low risk of compromise.” For anything other than a “low risk,” covered entities must notify

each affected or potentially affected individual, the Department of Health & Human Services’ Office for Civil Rights (OCR) and, for certain major breaches, local media outlets.

The default responsibility for breach notification is on the covered entity, although vendors and contractors

that utilize PHI (i.e., “business associates”) are obligated to notify their covered entity clients in the event of a breach. [4] Covered entities can also set stricter, more defined obligations for breach notification for their business associates and delegate notification responsibilities in their business associate agreements.

In determining whether notification is required, a risk assessment must account for at least the following four factors:

The nature and extent of the protected health information involved, including the types of identifiers and the likelihood of re-identification;

1. The unauthorized person who used the protected health information or to whom the disclosure was made;

2. Whether the protected health information was actually acquired or viewed; and
3. The extent to which the risk to the protected health information has been mitigated.[5]

These risk assessments are fact-specific analyses, based entirely on the facts and circumstances of the occurrence or event. For example, in 2016, OCR published guidance on HIPAA's application to ransomware attacks, the malware attacks where data is encrypted and held for ransom, and indicated that such attacks should be presumed to be a breach because they constitute an impermissible acquisition of the PHI.[6] Despite OCR's clear intent to treat ransomware attacks as breaches, OCR stopped short of calling all ransomware attacks breaches that require notification, stating that entities may still find that there is a "low risk of compromise" through a risk assessment.

Further, OCR has said that covered entities may skip the performance of a risk assessment and go right to notification. However, if a covered entity is unsure of whether a breach has occurred, a risk assessment reaching a good faith conclusion should be performed and documented.[7] The burden is on the covered entity to show that it fulfilled all regulatory requirements, so documentation should be

maintained in a place where it can be found in the event of an audit or investigation.

WHY DOES COMPLIANCE MATTER?

There is a simple reason why it is important to perform risk assessments: to make required notifications timely and correctly, and to document exceptions, risk assessments, and notifications appropriately. OCR enforcement activity has increased in the last few years, and many of the settlements published on OCR's website have resulted from investigations originating with one or more breaches.[8] This year, OCR issued its first settlement arising from late breach notification (just one month late!) for \$475,000.[9] As of August 31, 2017, the highest OCR settlement to date is \$5.55 million, with a total of almost \$73 million collected through settlements since enforcement began.[10]

CONCLUSION

The reality is that not all breaches are preventable, but the HIPAA Security Rule prescribes numerous measures that are designed to instill good data protection practices in covered entities and business associates. These measures include facility and software/hardware access security, malware protection, and employee training.[xi] Among the most important Security Rule

measures as to breach notification are those for encryption in transmission and at rest.[xii] Data that are encrypted are considered "secured" and, therefore, not subject to breach notification. [xiii] As OCR continues to actively enforce HIPAA, covered entities and business associates alike should reevaluate their compliance with all aspects of HIPAA, including the breach notification regulations.

For more information, please see our Health Care Data Aware Blog, which highlights current events, news and key legal and regulatory authorities and guidance related to health care data privacy and security, or contact me at 804.420.6609 or kmiller@williamsmullen.com.

[1] Pub. L. No. 104-191, 110 Stat. 1936 (1996) (as amended by the Health Information Technology for Economic and Clinical Health Act (HITECH Act) (Title XIII of Division A and Title IV of Division B of the American Recovery and Reinvestment Act of 2009 (Pub. L. 111-5)).

[2] 45 C.F.R. Parts 160 and 164, Subparts A and E (the "Privacy Rule"); 45 C.F.R. Parts 160 and 164, Subparts A and C (the "Security Rule").

[3] 45 C.F.R. 164.400 et seq.

[4] 45 C.F.R. 164.404-410.

[5] 45 C.F.R. 164.402.

[6] "FACT SHEET: Ransomware and HIPAA," available at <https://www.hhs.gov/sites/default/files/RansomwareFactSheet.pdf>

[7] "Breach Notification Rule," available at <https://www.hhs.gov/hipaa/for-professionals/breach-notification/index.html>.

[8] "Resolution Agreements," available at <https://www.hhs.gov/hipaa/for-professionals/compliance-enforcement/agreements/index.html>.

[9] "First HIPAA Settlement for Lack of Timely Breach Notification Settles for \$475,000," available at <https://www.hhs.gov/hipaa/for-professionals/compliance-enforcement/agreements/presence/index.html>

[10] <https://www.hhs.gov/hipaa/for-professionals/compliance-enforcement/data/enforcement-highlights/index.html>

[11] 45 C.F.R. 164.308-312.

[12] 45 C.F.R. 164.312(a)(2)(iv); 164.312(e)(2)(ii).

[13] 45 C.F.R. 164.402 (defining "Unsecured Protected Health Information").

NORTH CAROLINA STATE HEALTH COORDINATING COUNCIL VOTES ON PROPOSED 2018 STATE MEDICAL FACILITIES PLAN

By Joy Heath

On October 4, 2017, North Carolina's health planning body, the State Health Coordinating Council (SHCC), met in Raleigh to finalize its work on the document that will define health care opportunities in North Carolina for the year to come. The much-anticipated 2018 State Medical Facilities Plan (SMFP) will now be tendered for consideration by Governor Cooper.

The 2018 SMFP is expected to reveal long-awaited opportunities for the development of new operating rooms (ORs) in Counties across North Carolina. By identifying the need for new ORs in various locations, the 2018 SMFP will open the doors for hospital OR expansion projects or proposals for new freestanding ambulatory surgery centers. A flurry of activity is anticipated to follow the announcement of the OR need determinations in the 2018 SMFP. The 2018 SMFP is expected to reveal a need for six new ORs in Mecklenburg County. In the Triad, Forsyth County anticipates a significant OR need determination, while in the Piedmont, OR need determinations are expected for Wake, Durham and Orange Counties. Western North Carolina's Buncombe County (Asheville) is also expected to see a two OR need determination. Hospitals in

Mecklenburg, Moore and Orange Counties anticipate opportunities to apply for Certificate of Need (CON) approval for additional acute care beds in 2018.

In the Technology and Equipment arena, the 2018 SMFP is expected to offer a unique opportunity for CON approval of a new Mobile PET scanner with a statewide area of operation. The 2018 SMFP is also anticipated to include opportunities for the acquisition of new MRI scanners in Union County and in a multi-County coastal service area. New cardiac catheterization equipment is expected to be shown as needed in one or more market areas in the State.

In Long-Term Care, the 2018 SMFP is likely to keep a tight lid on new development opportunities with only limited openings for CON approval for adult care home beds in two rural counties. As in years past, the SMFP will force providers to look to the acquisition of existing nursing home and adult care home beds to satisfy their objectives in North Carolina.

Need determinations in the psychiatric and chemical dependency arena are likely to be minimal. The 2018 SMFP may show a need for chemical

dependency treatment beds for children and adolescents but not for psychiatric beds or adult chemical dependency treatment beds. Need determinations are not forecasted for other specialized medical equipment such as linear accelerators and lithotripters.

The 2018 SMFP is anticipated to offer several opportunities in home health and hospice. Two new home health agencies are expected to be shown as needed in the Wake County market. Also in Wake County, a need is expected for new hospice inpatient beds. In Cumberland County, a need is anticipated both for a hospice agency and hospice inpatient beds.

The 2018 SMFP will reveal opportunities in several key health care sectors and will provide a road-map for providers charting plans for growth and development in the coming year. Please let us know if you have any questions about the opportunities available in the 2018 SMFP.

SENIOR HOUSING TRANSACTIONS IN 2017

By James T. Bailey

Through the first three quarters of 2017, the market has continued to see steady deal flow in senior housing, with some sluggishness over the summer months. The dollar value of senior housing transactions for the first half of 2017 alone was over \$11 billion.[1] This article discusses recent trends in the senior housing industry from financial and transactional standpoints.

Senior housing already has experienced several different economic phases since the beginning of the 21st century. First, a boom market. Second, a recession characterized by falling occupancy and falling values. Then, a recovery phase with rising values tied to an expansion phase marked by still-rising occupancy, increasing rents, rising values and new construction.[2] Many experts believe we may have begun to enter a hyper-supply phase marked by declining occupancy, continued rapid construction and possible overbuilding.[3]

Overall occupancy in senior housing is at around 88.8%, with 90.6% occupancy in independent living, 86.6% occupancy in assisted living and 86.2% occupancy in nursing care. Annual inventory growth is the highest in assisted living at 5.9%, 2.5% in independent living and almost no inventory growth in nursing care, just 0.1%. While assisted living inventory growth is more than double

that of independent living, its occupancy levels are much lower than independent living. Perhaps troubling is the fact that annual absorption, the year-to-year percentage change in occupied units, in nursing facility units was -0.6%, which indicates excess supply in the market.[4]

Another metric that demonstrates growth in non-nursing facility senior housing is “construction versus inventory,” the number of units under construction divided by the inventory currently in the market. That metric reflects 3.9% in independent living, 8.2% in assisted living, but only 0.7% in nursing care. The overall construction as a percentage of inventory in senior housing is very high at 5.8%, again suggesting too much supply.

With both independent living and assisted living, annual inventory growth is outpacing annual absorption. Twelve markets have more than 10% of their inventory under construction, including: Fort Myers, Florida; Orlando, Florida; Jacksonville, Florida; Charleston, South Carolina; Atlanta, Georgia; Austin, Texas; Colorado Springs, Colorado; and Columbus, Ohio.

Not only are the number of assisted living and independent living beds growing, but so are the average rents with these units. Annual rent growth in independent living is 3.5%, annual rent growth in assisted living is 3.3% and annual rent growth in nursing care is only 2.6%. The cap rate, the net operating income divided by the property asset value, continues to



be significantly higher for nursing facility beds compared to assisted living beds, and the price for assisted living beds continues to be significantly higher than nursing facility beds. In the first quarter of 2017, the average nursing facility price per bed was \$97,900, and the cap rate was 11.9% (down from 12.2% in the previous quarter). The average assisted living price per bed was \$216,700 per unit with an 8.2% cap rate. Independent living was \$222,200 per unit with a 6.9% cap rate.

Those who follow the senior housing market note certain prevalent themes in 2017: (i) regardless of the possible oversupply across senior housing, the

values remain high particularly because of the low interest rates; (ii) with this transactional volume, bridge-to-HUD lending continues to experience massive growth; (iii) private operators, as a group, continue to be a large class of purchasers (41% of buyers were private operators, 28% were private equity groups, 26% were REITS and 2% were public companies in the last quarter); and (iv) growth continues to be strong in Florida, Texas and California, with notable growth in the D.C. and Hampton Roads markets. [5]

With the cost of capital remaining low, and rents remaining high, 2017 continues to be a busy year for senior housing transactions even if

there may be too much supply in the market. Assisted living facilities and independent living facilities continue popping up, and rental rates continue to rise. Even without much portfolio change in the third quarter, 2017 will surpass the \$14.4 billion of announced transactions in 2016. Regardless of the participant or the size of the transaction, Williams Mullen is ready to partner with market players ready for their next deal.

[1] However, the third quarter transaction value was only around \$2.54 billion.

[2] Peck, Lana, 2017 NIC Fall Conference: Investing in Senior Housing & Care Properties, 26 Sept. 2017, Sheraton Grand Hotel, Chicago, IL. Pre-Conference Workshop.

[3] Id.

[4] NIC MAP Data Service, 3Q17 NIC MAP Market Fundamentals.

[5] Acquisition Values Remain High and Stable, Aug. 2017, Vol. 29, Issue 8, The Senior Care Investor.

HEALTH CARE NEWSMAKERS



The Opioid Crisis: An interview with Mandy K. Cohen, MD, MPH, Secretary of the N.C. Department of Health and Human Services

What is the opioid crisis and how did we get here?

The opioid crisis is a devastating and complex issue. We arrived here on a path paved with good intentions. Twenty years ago, clinicians were encouraged to treat pain more aggressively, sometimes without proper safety guidelines or training. Similarly, patients were incorrectly counseled that pain could be easily controlled by opioids without any long-term side effects. We now know that these practices - along with a series of other complex factors - led us to where we stand today.

How bad is the opioid crisis in North Carolina?

Since 1999, over 13,000 North Carolinians have died from an opioid overdose. And the number of deaths have increased year-over-year. In 2016, an estimated 1,360 North Carolinians died from an unintentional overdose. This is 25 percent more than in 2015 and a greater than ten-fold increase

since 1999. This harrowing statistic doesn't even account for the more than 13,000 opioid overdose reversals using naloxone by our EMS and first responders.

What are the effects on our state?

Besides the tragic loss of life and the heavy toll of addiction felt by countless individuals, the opioid crisis is also affecting our families and kids. In the last five years, North Carolina has seen a 25 percent increase in the number of children in foster care. In addition, we are seeing more pregnant women fighting opioid addiction. North Carolina has seen a nearly 900 percent increase in hospitalizations associated with drug withdrawal in newborns over the last ten years.

How has this epidemic changed over time?

People have progressed from prescription opioids to heroin and fentanyl. Since 2010, we've seen an over 800 percent increase in deaths from heroin and these statistics will only get worse as the use of more deadly fentanyl is expected to increase. More than half of all opioid overdose deaths now involve these illicit drugs.

Is the opioid crisis worse in North Carolina than other states?

It is worse here in North Carolina because many people struggling with mental health and substance use disorders do not have health insurance and therefore treatment. A major step North Carolina could take to turn the tide on the opioid crisis is to access the additional federal dollars to provide insurance coverage to working folks in North Carolina. This would allow our state to receive nearly \$4 billion in federal dollars to increase access to insurance coverage for over 500,000 folks in our state.

What can we do to turn the tide on the opioid crisis?

There has been good work done all over the state to combat the opioid crisis. Over the last 10 years, North Carolina has:

- > launched a Prescription Drug Monitoring Program to address prescription drug abuse, addiction and diversion;
- > introduced Operation Medicine Drop, which has since become the largest drug take-back program in the U.S.;

- > passed the Good Samaritan/ Naloxone Access Law, allowing our EMS, law enforcement and other first responders to distribute and carry naloxone reversing thousands of overdoses; and
- > issued a Statewide Standing Order for naloxone, allowing any person at risk of experiencing an opiate-related overdose or a family member or friend of someone at risk, to get naloxone from a pharmacy without a prescription.

This year, Governor Roy Cooper also signed the bipartisan STOP Act, which limits doctors to prescribing no more than five days of opioids for acute pain — such as a broken bone — and requires providers to utilize the state’s Controlled Substance Reporting System to monitor prescriptions.

I am encouraged by the great work that has been done across the state by our partners and am very proud of their work to turn the tide on the opioid epidemic. But despite all this hard work, the crisis is getting worse.

That’s why in June, we launched North Carolina’s Opioid Action Plan. The intent of the Plan is to catalogue specific, tangible, achievable steps that will have the greatest impact on reducing the burden of death from the opioid epidemic and the partners in North Carolina that are engaging in this work. Our goal is to change the trajectory of opioid deaths and reduce opioid overdose deaths by 20 percent by 2021.

To date, we have made great progress on this plan—including purchasing nearly 40,000 units of lifesaving naloxone and making

changes to our Medicaid program to allow people to start on suboxone, a medication-assisted treatment, immediately without prior authorization. We are also using federal and state grant dollars and allocations to get more people with an opioid-use disorder into treatment. While we have made great progress, we know that until we get more people access to health insurance and therefore get them access to long-term treatment and recovery services, we will not fully turn the tide on this crisis.

Tell us about North Carolina’s Opioid Action Plan.

We know the necessary steps to turn the tide on this crisis. That is why we released North Carolina’s Opioid Action Plan, a coordinated plan to get partners and stakeholders around the state centered on one goal — to reduce opioid overdose deaths by 20 percent over the next five years. Under this plan, North Carolina will: (1) create a coordinated infrastructure, (2) reduce oversupply of prescription opioids, (3) reduce diversion of prescription drugs and flow of illicit drugs, (4) increase community awareness and prevention, (5) make naloxone widely available and link overdose survivors to care, (6) expand treatment and recovery-oriented systems of care, and (7) measure our impact and revise strategies based on results.

How can DHHS turn the tide on the opioid crisis through the Medicaid program?

As part of the overall North Carolina’s Opioid Action Plan, we recognize the important role health care payers can play in addressing the opioid epidemic and improving health outcomes through benefit design, member

services and pharmacy policies. DHHS has been proactive and has made policy changes to promote safe opioid prescribing, non-opioid pain management, and access to naloxone for patients covered by Medicaid and Health Choice and will continue to consider other policy changes to improve health outcomes. For example, the Medicaid program removed the prior authorization requirement for suboxone, a medication-assisted treatment option, which allows Medicaid patients to start treatment immediately.

In addition to our work within Medicaid and Health Choice, we will convene a Payer’s Council to bring together public and private payers with a goal of identifying, aligning and implementing policies that:

- > Support providers in the judicious prescribing of opioids;
- > Promote safer and more comprehensive alternatives to pain management;
- > Improve access to naloxone, substance use disorder treatment and recovery supports; and
- > Engage and empower patients in the management of their health.

HEALTH CARE NEWSMAKERS



Please tell us a little bit about Patient First and your responsibilities there.

Patient First provides primary and urgent care medical services at 73 medical centers located in Virginia, Maryland, Pennsylvania and New Jersey. Patient First centers are open on a non-appointment basis from 8 a.m. to 10 p.m. 365 days a year, including weekends and holidays. In addition to physician services, our on-site services include moderate complexity clinical laboratory tests, digital x-rays, and dispensing from a formulary of over 100 commonly-prescribed drugs. We employ 600 physicians and physician extenders, with a physician on site and seeing patients at each location during all hours of operation, as well as hundreds of nurses, lab and x-ray technicians, medical assistants and clerical staff. We focus on helping patients return to their lives and work as soon as possible.

As general counsel, I'm responsible for oversight of Patient First's

Physician Practice Payment Reimbursement Reform and Strategies: An interview with Steve McCoy, Vice President/General Counsel, Patient First

legal and regulatory compliance; contract review and management; federal and state legislative review, advocacy, and relations; privacy and security initiatives; and litigation and risk management. Like most of my colleagues at Patient First, I wear a lot of hats but I'm fortunate to have good help, both internal and external.

With all the discussion lately about trying to manage the cost of healthcare, what are the most important recent changes in reimbursement methodology and strategies which Patient First has seen in the market?

The ongoing transition away from fee-for-service toward value-based reimbursement is probably the most important ongoing trend for all providers, not just physician medical practices like ours. That's particularly true as government and commercial payers begin to move toward mandatory risk-sharing. We've participated in both the CMS EHR Incentive Program and Physician Quality Reporting System for the past several years, and are in our first reporting period under MACRA's Merit-Based Incentive Payment System (MIPS) that replaces those initiatives now. I would expect

the ongoing development both of MIPS measures and categories (including the introduction of cost measures into MIPS scoring) and of Alternative Payment Models to have substantial impact on our organization going forward.

Have those Medicare initiatives transferred over to the commercial insurance market?

Yes, commercial payers are steadily integrating value-based reimbursement into their reimbursement models and moving toward risk-sharing models. We've been involved with commercial value-based reimbursement since 2011 and have seen a number of variations on both primary and urgent care incentive programs in our markets, with payers focused initially on cost and utilization but transitioning over time to clinical outcomes evaluation and measurement.

What benefits have those new physician reimbursement protocols and strategies brought to your company and the public?

The benefit to the public of a properly-constructed program to identify and reward value-based care is obvious: if we can reduce

costs and improve outcomes, everyone wins. The challenge, of course, is selecting and pacing program initiatives and rewards to maintain provider engagement and help all of the participants (patient, payer, provider) succeed.

The focus on value-based care provides an ongoing opportunity for us to talk about the value that Patient First brings to the patient, health care provider, and payer communities. Our medical center physicians and extenders routinely treat almost two-thirds of the diagnoses that are treated in hospital emergency rooms, at a fraction of the cost. We also believe that the patient experience is substantially improved when a laceration or other urgent but non-emergent trauma is treated in an urgent care center rather than a hospital emergency department, and that our hospital colleagues benefit when their over-stressed emergency departments are not tasked with treatment of patients who do not require true ED-level care.

One predictable but nevertheless welcome benefit of the shift away from fee-for-service is the ongoing conversation about coordination of care across the continuum and appropriate location of care that we are having with hospitals, payers and other community providers. Again, if we can “right-size” care, the patient, provider, employer and insurance communities all stand to benefit.

What risks and concerns have those initiatives required large physician practices like Patient First to face?

Any transition in reimbursement from a long-established model to a

somewhat theoretical replacement will cause concern. The challenge to Patient First is similar to that facing other providers: finding a way to manage the transition in a manner that allows us both to succeed now and to be ready for the future.

Another challenge that is somewhat peculiar to Patient First is the need to integrate our sizeable, multi-state physician, extender and clinical staff into value-based care initiatives without interfering with their ability to treat patients efficiently and well. Meaningful Use, MIPS and commercial incentive programs are hard enough to understand and implement when you are trying to do so from an office desk; actually doing it in the treatment room is more difficult.

Finally, we see a real need for some degree of standardization among these programs. As one of my colleagues likes to say, “across government and commercial payers, if you’ve seen one program, you’ve seen one program.” For example, every payer’s choice of clinical quality, cost and utilization metrics is different. We recognize that innovation in care delivery is a trial and error process by necessity (and likely by design), but for these programs to succeed, the provider community needs a degree of consensus and consistency.

We know Medicare and the commercial insurance market have spent the last decade actively wrestling with physician payment reform measures. What are a few opportunities and concerns which you see going forward?

The opportunity is to create some true alignment of medical care

among the provider and payer communities. As an intermediate-level provider, we have worked with local hospitals and physician practices in our markets since 1983 to coordinate care and transition patients appropriately among various settings and to share information efficiently. As payment models incentivize and reward care management across the spectrum of settings, I’d like to think that some measure of competition will yield to coordination of care among health care providers.

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