IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF VIRGINIA
ABINGDON DIVISION

UNITED STATES OF AMERICA, ET AL.,	)	
Plaintiffs,	)	Case No. 1:21CV00032
v.	)	**OPINION AND ORDER**
WALGREEN CO.,	)	JUDGE JAMES P. JONES
Defendant.	)	

Justin Lugar, Assistant United States Attorney, Roanoke, Virginia, for Plaintiff United States of America; William Clay Garrett and Caitlyn Huffstutter, Assistant Attorneys General, VIRGINIA OFFICE OF THE ATTORNEY GENERAL, Richmond, Virginia, for Plaintiff Commonwealth of Virginia; Jonathan M. Phillips and Michael R. Dziuban, GIBSON, DUNN & CRUTCHER LLP, Washington, D.C., and Reed Brodsky, GIBSON, DUNN & CRUTCHER LLP, New York, New York, for Defendant Walgreen Co.; Jonathan A. Henry, Jeffrey S. Bucholtz, and Jeremy M. Bylund, KING & SPALDING LLP, Washington, D.C., for Amicus Curiae Chamber of Commerce of the United States of America.

In this civil case brought by the United States and Virginia alleging violations of the False Claims Act as well as state law claims, defendant Walgreen Co. ("Walgreens") has moved to dismiss for failure to state a claim upon which relief can be granted.

In summary, the plaintiffs claim that from January 2015 through July 2016, Amber Reilly, a Clinical Pharmacy Manager at a Walgreens pharmacy in Kingsport, Tennessee, and another employee at her direction, changed data on

forms and falsified laboratory test results in order to obtain preauthorization for reimbursement for hepatitis C medications that Walgreens provided to Virginia Medicaid recipients. Those who received the drugs had been diagnosed with hepatitis C and had been prescribed the medications by their respective healthcare providers. They did not, however, meet certain disease severity and alcohol and drug abstinence requirements that Virginia Medicaid had adopted as prerequisites for reimbursement These preauthorization requirements were in place because the drugs were expensive in light of Virginia Medicaid's limited budget. The claims at issue would not have been paid had Reilly not submitted, or directed the submission of, falsified documents.

Walgreens has not reimbursed Virginia Medicaid for any of the nearly $800,000 paid to Walgreens based on its employees' false representations. Walgreens contends that the false representations were not material because Virginia Medicaid's exclusion requirements for these drugs were in violation of federal law.

For the reasons set forth in this Opinion, I agree with Walgreens' position and will grant its Motion to Dismiss.[1]

[1] Walgreens also argues that it cannot be vicariously liable for the actions of its employees involved, but it is not necessary for me to decide this issue.

I.

The following facts are alleged in the plaintiffs' 56-page Complaint, which I must accept as true for purposes of deciding Walgreens' Motion to Dismiss.

The United States, through its Department of Health and Human Services ("HHS"), administers grants to states for Medical Assistance Programs, commonly known as Medicaid, pursuant to Title XIX of the Social Security Act, 42 U.S.C. §§ 1396–1396w-6. The Virginia Department of Medical Assistance Services ("DMAS") administers the Virginia Medicaid program, which is a jointly funded federal and state program. Like all participating states, Virginia submitted to HHS a plan for administering its Medicaid program, which explained how the state would meet applicable federal rules and regulations.

Walgreens owns and operates more than 9,000 pharmacies throughout the United States. Walgreens was a registered Virginia Medicaid provider during the relevant time period. The Walgreens Specialty Pharmacy located in the Holston Valley Medical Center in Kingsport, Tennessee, where Reilly worked, billed DMAS for prescription drugs and other services.

DMAS contracted with Magellan Medicaid Administration ("Magellan") to administer the claims submitted for its fee-for-service ("FFS") program. Magellan's duties included determining whether patients satisfied DMAS coverage

eligibility criteria for expensive prescription drugs. DMAS directly reimburses providers, such as Walgreens, for services provided to its FFS recipients.

DMAS also contracts with Managed Care Organizations ("MCOs") to provide prescription drugs and other services to Virginia Medicaid recipients. Individuals enrolled in managed care plans receive payment from the MCOs, and DMAS pays the MCOs a fixed monthly fee for each enrollee. Each MCO then contracts with drug providers and pays the drug providers with funds received from DMAS. During the relevant time period, DMAS had contracted with two MCOs, Virginia Premier Health Plan, Inc. ("Virginia Premier") and Aetna Better Health of Virginia ("Aetna").[2] Virginia Premier contracted with a Pharmacy Benefits Manager ("PBM"), EnvisionRX Options, to collect and review documents for prior authorization. The MCOs determined whether patients met DMAS's criteria for coverage of relevant drugs. Both FFS claims and managed care plan claims were paid with funds provided by the Commonwealth of Virginia and HHS.

To participate in Virginia Medicaid, providers like Walgreens must execute a participation agreement in which they agree to adhere to the policies and regulations set forth in DMAS Provider Manuals, including documentation requirements and billing rules, and to comply with applicable state and federal

[2] For part of the relevant time period, Aetna contracted with DMAS under the name CoventryCares.

laws. The Walgreens store at which Reilly worked entered into such a participation agreement on October 21, 2010.

During the relevant time period, DMAS required prior authorization for certain prescription drugs. A prescribing practitioner was required to complete a prior authorization form for an individual patient. The form asked a number of detailed questions about the patient's medical history, and the provider had to submit laboratory reports and drug test results supporting the answers to the questions. DMAS reviewed this information to determine whether the patient met eligibility criteria in order for the claim to be paid and notified the prescriber of its decision. Prior authorization was required for certain drugs used to treat hepatitis C, namely Sovaldi 400 MG tablets, Harvoni 90 MG-400 MG tablets, and Daklinza 60 MG tablets (collectively, the "relevant drugs").[3] Absent prior approval for these drugs, claims for them would be denied. A full course of treatment with one of the relevant drugs could cost DMAS as much as $96,000.

During the relevant time period, claims based on the relevant drugs were reimbursable for patients whose fibrosis stage (also called metavir stage) was F3 or F4, but not those whose stage was F0, F1, or F2. The claims were reimbursable for patients who had fibrosis scores of greater than or equal to 0.59. The metavir

[3] Magellan did not begin requiring prior authorization for Daklinza 60 MG tablets for Medicaid FFS recipients until January 1, 2016. Aetna and Virginia Premier began requiring prior authorization for this drug for Medicaid managed care plan patients in July 2015.

stages and fibrosis scores were indicators of liver damage caused by hepatitis C. The claims for the relevant drugs were also reimbursable for patients who had documented cirrhosis. The claims were reimbursable only for patients who had not used drugs or alcohol in the prior six months, as confirmed by urine drug screen results or physician certification.

Reilly sometimes held herself out to be a "patient care advisor" with Physician Group 1 when submitting documentation to DMAS. Compl. ¶ 51, ECF No. 1. She was not employed by Physician Group 1; she was only employed by Walgreens. Reilly was not authorized to sign the name of any employee of Physician Group 1 on documentation submitted to DMAS. Reilly approached a nurse practitioner at Physician Group 1 ("NP 1") and offered to complete the insurance paperwork for the practice's hepatitis C patients if Physician Group 1 filled the prescriptions through Reilly's Walgreens store. NP 1 agreed but did not give Reilly authority to sign her name or to write appeal letters on NP 1's behalf without NP 1 first reviewing the letter.

The revenue of Reilly's Walgreens store was $1,589,528 in February 2015, the first month in which Walgreens received payment based on falsified documentation submitted by Reilly or at her direction. In May 2016, the store's revenue was $5,098,765. The store's revenue increased by more than 320% in just 15 months. "This staggering revenue increase resulted from dramatic increases in

revenues from payments by government payors, including DMAS, for hepatitis C drugs." *Id.* ¶ 55.

During a performance review for the year ending August 31, 2015, Reilly told her manager, Charles Wykes, "I know what each payor requires for approval, [. . .] and I've became [*sic*] an expert in customizing appeal letters based on a plan's criteria. This knowledge has been crucial in receiving approvals, which in return, has increased profits and strengthened relationships with providers." *Id.* ¶ 56. Wykes stated, "[Reilly] has not only created loyal customers, but has created very loyal Dr offices and case managers and has developed our site to have a reputation of one that will go the extra mile. She [. . .] must present in a way that gains trust because I have witnessed her detail one day and the next gain several referrals from the office." *Id.*

By June 2016, Walgreens "was on notice that it had received payments based on false statements and documents submitted or caused to be submitted and that it had an obligation to reimburse DMAS for such overpayments." *Id.* ¶ 57. That month, the Tennessee Bureau of Investigation ("TBI") served Walgreens with subpoenas seeking records related to prescriptions filled for certain patients. On June 15, 2016, Walgreens' loss prevention personnel went to Reilly's store to investigate, and they obtained records that had been altered. An employee

admitted to loss prevention personnel that she had falsified prior authorization records at Reilly's direction.

In October 2016, Reilly pled guilty in the United States District Court for the Eastern District of Tennessee to the crime of health care fraud, 18 U.S.C. § 1347. She admitted that she had falsified, and directed another employee to falsify, prior authorization paperwork, laboratory reports, and drug test results to secure coverage for the relevant drugs for patients who did not satisfy coverage eligibility criteria.

Reilly's conduct increased the total number of prescriptions filled at her Walgreens store as well as the store's customer satisfaction ratings. These factors were part of Walgreens' formula for calculating bonuses. Reilly's falsification of prior authorization documents therefore likely increased her chances of receiving bonuses and the amount of her bonuses.

DMAS's Pharmacy Manual requires providers to "refund payments made by Medicaid if they are found to have billed Medicaid contrary to law or regulation, failed to maintain any record or adequate documentation to support their claims, or billed for medically unnecessary services." *Id.* ¶ 64 (quoting DMAS Pharmacy Policy Manual, Chapter VI at 2 (last updated Dec. 16, 2015)).

Walgreens has not refunded any payments to DMAS that were made based upon falsified documentation. Falsified preauthorization documents were submitted to

DMAS for at least twelve patients, and Virginia Medicaid paid Walgreens at least $793,908.95 for drugs that the patients were not then eligible to receive under Virginia Medicaid's prior authorization criteria.

Patient 1, a Virginia Medicaid FFS recipient, had hepatitis C and was treated by a physician with Physician Group 1 (MD 1). MD 1 completed or caused to be completed Walgreens' Prescription/Pharmacy intake form for Patient 1. Walgreens responded the next day, stating "we . . . will work on [Patient 1's] prior authorization." *Id.* ¶ 69. Walgreens submitted a prior authorization request to DMAS for Patient 1 for Sovaldi 400 MG tablets. The prior authorization form stated that Patient 1's fibrosis score was greater than or equal to 0.59. The form contains a signature purporting to be that of MD 1, but this signature does not match MD 1's signature on the intake form, and MD 1 has stated that he/she did not sign the form.

DMAS responded to the prior authorization form by requesting additional information to confirm Patient 1's disease severity and abstinence from drugs and alcohol. Walgreens then submitted a falsified report for laboratory work processed by Solstas Labs. On the form submitted to DMAS, the fibrosis score is smudged and a score of 0.62 is written by hand. The submitted report lists a fibrosis stage of F3, and the notes section reads, "fibrosis." *Id.* ¶ 73. In contrast, the original laboratory report lists a fibrosis score of 0.42, a fibrosis stage of F1-F2, and a note

that reads, "minimal fibrosis." *Id.* ¶ 74. Walgreens had the actual laboratory report in its possession no later than August 3, 2016.

By August 2016, Walgreens had obtained accurate records for Patient 1 from Physician Group 1. Those records did not contain any laboratory reports or test results that would have met Virginia Medicaid's eligibility criteria for coverage of Sovaldi.

On May 4, 2016, DMAS approved the claim for Sovaldi for Patient 1 based on the falsified documentation. The claim would not have been paid if not for the forged fibrosis score, fibrosis stage, and note regarding fibrosis on the laboratory report. In total, Virginia Medicaid paid Walgreens $87,593.70 for Sovaldi for Patient 1. Walgreens has not repaid any of those funds.

Patient 2 was a Virginia Medicaid recipient who had hepatitis C and was treated by a physician at Physician Group 1 (MD 2). Patient 2 was prescribed both Daklinza and Sovaldi. MD 2 completed Walgreens' Physician/Pharmacy intake form for Patient 2 on February 2, 2016. Walgreens submitted a prior authorization request to DMAS on February 5 on behalf of Patient 2, seeking coverage for both Daklinza and Sovaldi. The request listed a metavir score of F3-F4 and a fibrosis score of greater than or equal to 0.59. The submitted form included the following note: "patient started on Peg/Ribavirin in 2011 [and] had to stop due to reaction to Ribavirn." *Id*. ¶ 85. MD 2 neither wrote this note nor instructed or allowed

Walgreens to include this note on the form. The form includes a signature purportedly of MD 2, but MD 2 did not sign the form and the signature does not match MD 2's signature on the Prescription/Pharmacy intake form.

On February 8, DMAS requested additional information to substantiate Patient 2's request. Walgreens then submitted a laboratory report purportedly from Takoma Medical Associates showing a collection date of January 27, 2016. The patient information on the report was falsified and had been substituted onto the report of a different person. Handwritten onto the submitted laboratory report were a fibrosis score of 0.68 and a metavir score of F3. Neither Physician Group 1's records nor DMAS's billing records indicate that Patient 2 had been treated at Takoma Medical Associates.

Walgreens also submitted a Solstas Labs report dated January 21, 2016. Here, too, Patient 2's name and date of birth had been superimposed onto Hepatitis Acute Panel results for another individual. Records of both DMAS and Solstas Labs indicate that no laboratory work was done by Solstas Labs for Patient 2 in January 2016. Solstas Labs had performed a Hepatitis Acute Panel for this patient in August 2015, but those results were inconsistent with the report submitted to DMAS.

In addition, Walgreens submitted the results of a CT Abdomen Without and With Contrast dated December 2015, which contains no patient identifying

information. The report does not list a facility where the CT was performed. The report indicates that the patient's liver is "markedly cirrhotic in appearance" and that there are "significantly cirrhotic changes of the liver noted." *Id.* ¶ 95. DMAS was never billed for a CT Abdomen scan on Patient 2 performed in December 2015, and Physician Group 1's file for Patient 2 contains no record of such a procedure.

"On February 9, 2016, relying on the false claims submitted or caused to be submitted by Walgreens, DMAS approved the prior authorizations for Patient 2." *Id.* ¶ 98. Absent submission of the falsified fibrosis and metavir scores and altered laboratory and CT reports, the claims would not have been paid. In total, Virginia Medicaid paid Walgreens $93,865.60 for Daklinza and Sovaldi for Patient 2, and Walgreens has not repaid any of those funds.

The Complaint makes similar allegations regarding preauthorization requests for ten other patients, Patients 3 through 12.

The Complaint alleges that, "[u]pon information and belief, Walgreens took steps to identify the payments that were made to Walgreens from Virginia Medicaid as a result of Reilly's submissions of false claims as early as June 2016." *Id.* ¶ 261. Walgreens began an "internal process" in June and July 2016, weeks after Reilly was terminated, "that identified payments for Virginia Medicaid recipients that were impacted by Walgreens' fraudulent submissions." *Id.* ¶ 262.

"Upon information and belief, the internal investigation included obtaining patient records from health care providers for the relevant Virginia Medicaid recipients." *Id.* ¶ 263. "On July 26, 2016, a representative from [Reilly's Walgreens store] emailed an employee of Physician Group 1, seeking to obtain Physician Group 1's records regarding the fibrosis scores or liver biopsy results for Virginia Medicaid recipients treated by Physician Group 1." *Id.* ¶ 264. The plaintiffs allege, "[u]pon information and belief," that Walgreens "obtained accurate information" for these patients. *Id.*

Virginia issued a subpoena duces tecum to Walgreens requiring the production of all documents, records, and communications relating to Virginia Medicaid recipients who received the relevant drugs from Reilly's Walgreens location beginning on July 1, 2013. The records Walgreens produced in response show that Walgreens had accurate records for Patients 1 through 12 in its possession by August 2016 which indicated that these patients did not meet the Virginia Medicaid eligibility criteria for the relevant drugs. Walgreens' internal records also show that as early as June 2016, it initiated an investigation into prescriptions for the relevant drugs filled by Reilly's store. By June 2016, high-level Walgreens employees — including the Director of Asset Protection Solutions, Manager of Asset Protection Solutions, Manager for Quality Assurance and Patient Safety, and Area Healthcare Supervisor for the region — possessed

patient and prescription data for Patients 1 through 12. This information "included patient names, prescriber information, the relevant insurance plan, including information on the responsible MCO, as well as Walgreens' cost of filling the prescriptions, Walgreens' revenue from filling the prescription, and Walgreens' profit from the prescription." *Id.* ¶ 269.

The Complaint alleges, "[u]pon information and belief," that no one from Walgreens contacted anyone with the Virginia government to discuss returning the fraudulently obtained funds before June 2017 and that the first contact between Walgreens and a Virginia government representative occurred in September 2017. *Id*. ¶270. The Complaint further alleges that, "[u]pon information and belief," Walgreens has never contacted DMAS or its contractors to discuss returning the payments. *Id*. ¶ 271.

Based on these facts, the Complaint asserts ten claims against Walgreens: Making a False Claim in violation of the False Claims Act (FCA), 31 U.S.C. § 3729(a)(1)(A) (Count I); Knowingly Making or Using a False or Fraudulent Record Material to a False or Fraudulent Claim in violation of the FCA, 31 U.S.C. § 3729(a)(1)(B) (Count II); Reverse False Claims in violation of the FCA, 31 U.S.C. § 3729(a)(1)(G) (Count III); Making a False Claim in violation of the Virginia Fraud Against Taxpayers Act (VFATA), Va. Code Ann. § 8.01-216.3(A)(1) (Supp. 2021) (Count IV); Knowingly Making or Using a False or

Fraudulent Record Material to a False or Fraudulent Claim in violation of VFATA, Va. Code Ann. § 8.01-216.3(A)(2) (Supp. 2021) (Count V); Reverse False Claim in violation of VFATA, Va. Code Ann. § 8.01-216.3(A)(8) (Supp. 2021)[4] (Count VI); violation of the Virginia Medicaid Fraud Statute, Va. Code Ann. § 32.1-312 (2018) (Count VII); Unjust Enrichment (Count VIII); Payment by Mistake (Count IX); and Common Law Fraud (Count X).

Walgreens has attached several documents to its Motion to Dismiss. It asks me to take judicial notice of the following records.

In November 2015, the Center for Medicaid and CHIP Services of the Centers for Medicare and Medicaid Services (CMS) of HHS issued a letter titled *Assuring Medicaid Beneficiaries Access to Hepatitis C (HCV) Drugs* (Release No. 172, Nov. 5, 2015). The letter directly addressed state-imposed preauthorization requirements for the relevant drugs. It advised state Medicaid programs that if they had opted to cover prescription drugs, they were "required to comply with the requirements of section 1927(d)(1) and (2) of the [Social Security Act ("Act")]." Mem. Supp. Mot. Dismiss, Dziuban Decl. Ex. A at 1, ECF No. 9-3. The letter further stated that states must comply with § 1927(d)(4)(C) of the Act.

> Under this provision, a covered outpatient drug may only be excluded with respect to the treatment of a specific disease or condition for an

[4] The Complaint in fact cites section 8.01-216.3(A)(7) rather than section 8.01-216.3(A)(8), containing the reverse false claims provision of VFATA. I assume that this subsection reference was a typographical error.

> identified population if, based on the drug's labeling, . . . the excluded drug does not have a significant, clinically meaningful therapeutic advantage in terms of safety, effectiveness, or clinical outcome of such treatment for such population over other drugs included in the formulary and there is a written explanation (available to the public) of the basis for the exclusion.
>
> Accordingly, to the extent that states provide coverage of prescription drugs, they are required to provide coverage for those covered outpatient drugs of manufacturers that have entered into, and have in effect, rebate agreements described in section 1927(b) of the Act, when such drugs are prescribed for medically accepted indications, including the new DAA HCV drugs.

Id. at 2. The letter goes on to state,

> CMS is concerned that some states are restricting access to DAA HCV drugs contrary to the statutory requirements in section 1927 of the Act by imposing conditions for coverage that may unreasonably restrict access to these drugs. For example, several state Medicaid programs are limiting treatment to those beneficiaries whose extent of liver damage has progressed to metavir fibrosis score F3, while a number of states are requiring metavir fibrosis scores of F4.
>
> Certain states are also requiring a period of abstinence from drug and alcohol abuse as a condition for payment for DAA HCV drugs. . . .
>
> While states have the discretion to establish certain limitations on the coverage of these drugs, such as preferred drug lists and use of prior authorization processes, such practices must be consistent with requirements of section 1927(d) of the Act to ensure appropriate utilization.
>
> As such, the effect of such limitations should not result in the denial of access to effective, clinically appropriate, and medically necessary treatments using DAA drugs for beneficiaries with chronic HCV infections. States should, therefore, examine their drug benefits to ensure that limitations do not unreasonably restrict coverage of effective treatment using the new DAA HCV drugs.

Id. at 2–3 (footnotes omitted).

Walgreens has also submitted DMAS's Service Authorization (SA) Form Hepatitis C Antivirals: Preferred ("SA Form - Preferred") and Service Authorization (SA) Form Hepatitis C Antivirals: Non-Preferred ("SA Form - Non-Preferred"). Dziuban Decl. Exs. B, C, ECF Nos. 9-4, 9-5. Finally, Walgreens has submitted the State Plan Under Title XIX of the Social Security Act Medical Assistance Program ("State Plan"), which states that Virginia agrees to administer its state Medicaid plan in compliance with Title XIX of the Act. Dziuban Decl. Ex. D at 1, ECF No. 9-6.

In response to the Motion to Dismiss, the plaintiffs have filed a number of documents as well. The first is the Virginia Medicaid Preferred Drug List with Service Authorization Criteria (Effective January 1, 2015). Joint Resp. Opp'n Attach., Allen Decl. Ex. A, ECF No. 24-2. This document lists Sovaldi and Harvoni as non-preferred hepatitis C agents. *Id.* at 12–13. The plaintiffs have also filed the revised version of this list, effective July 1, 2015, which again lists Sovaldi and Harvoni as non-preferred agents. Allen Decl. Ex. B at 12–13, ECF No. 24-3. The plaintiffs have additionally filed the revised version, effective August 19, 2015, which continues to list Sovaldi and Harvoni as non-preferred agents. Allen Decl. Ex. C at 12, ECF No. 24-4.

Next, the plaintiffs have filed the version of this list, effective January 1, 2016. Here, too, Sovaldi and Harvoni are listed as non-preferred agents, but Daklinza is listed as a preferred agent. This version lists the requirements that the "Patient must have documentation of Disease Severity (Metavir Score F3 - F4) AND/OR Highest Risk for Disease Progression," and the "Patient must be evaluated for current history of substance and alcohol abuse, attested to by the prescribing physician(s)." Allen Decl. Ex. D at 12, ECF No. 24-5. The next version, effective April 1, 2016, contains the same listing designations and requirements. Allen Decl. Ex. E at 12, ECF No. 24-6. The next revision of the list, effective July 1, 2016, states

- Patient must have documentation of Disease Severity (Metavir Score F2 – F4) and/or at high risk of disease progression. In addition, documentation of a Metavir Score will not be required if a patient;
    - has a comorbid disease including HIV, hepatitis B or serious extra hepatic manifestations such as cryoglobulinemia, membranoproliferative glomerulnephrits: OR
    - has renal failure, is on dialysis or has a liver transplant; OR
    - is diagnosed with Genotype 3 hepatitis C

Allen Decl. Ex. F at 12–13, ECF No. 24-7. The requirement for evaluation of substance and alcohol abuse remains in this version.

The version of the Virginia Medicaid Preferred Drug List with Service Authorization Criteria effective on January 1, 2017, more than six months after

Reilly's termination, lists Harvoni as a preferred agent and Daklinza and Sovaldi as non-preferred agents. Allen Decl. Ex. G at 16, ECF No. 24-8. This revised list does not include any requirement regarding the metavir stage, and while it retains a requirement for the prescriber to evaluate the patient for substance use, it expressly provides that a "Member cannot be denied Hepatitis C treatment for sole reason of substance abuse." *Id.*

Finally, the plaintiffs have filed a Medicaid Memo dated December 1, 2017, from the Director of DMAS to prescribing providers, pharmacists, and MCOs participating in Virginia Medicaid. This memorandum lists Harvoni as a non-preferred drug requiring service authorization. Allen Decl. Ex. H at 2, ECF No. 24-9. The Medicaid Memo states,

> Effective January 1, 2017, the P&T Committee eliminated the fibrosis scoring (Metavir) requirement as a part of the approval process for all drugs used to treat Hepatitis C. However, prescribers must complete a **clinical** service authorization (SA) for all Hepatitis C drugs including the preferred drug, Mavyret™. The Committee approved an abbreviated clinical SA for Mavyret™ that requires the prescriber to document the HCV genotype, the member's previous Hepatitis C treatment experience, the extent of liver damage (Metavir score) and the completion of a Hepatitis C Patient Agreement. If Mavyret is not clinically indicated for a member, prescribers can complete a service authorization for a non-preferred Hepatitis C agent.

Id. at 3.

Subject-matter jurisdiction of this court is based on 28 U.S.C. §§ 1331 and 1345 for the counts of the Complaint based on the FCA, and supplemental jurisdiction over the state law claims under 28 U.S.C. § 1367(a).[5]

II.

In ruling on a motion to dismiss, the court may consider documents incorporated into the complaint by reference and matters of which a court may take judicial notice. *Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 322 (2007). Federal Rule of Evidence 201(b) provides,

> The court may judicially notice a fact that is not subject to reasonable dispute because it:
>
> > (1) is generally known within the trial court's territorial jurisdiction; or
> >
> > (2) can be accurately and readily determined from sources whose accuracy cannot reasonably be questioned.

The court "must take judicial notice if a party requests it and the court is supplied with the necessary information." Fed. R. Evid. 201(c)(2). For example, the Fourth Circuit recently took judicial notice "of the fact of the publication of" an opinion

[5] While I could decline to accept jurisdiction over the state law claims and dismiss them without prejudice, I find it appropriate to decide those claims because they "arise out of the same interrelated series of events or transactions and derive from a common nucleus of operative facts." *IntraComm, Inc. v. Bajaj*, 492 F.3d 285, 290 n.1 (4th Cir. 2007) (internal quotation marks and citation omitted). Moreover, the state common law claims do not "raise[] a novel or complex issue of State law" or "substantially predominate[]" over the other claims. 28 U.S.C. § 1367(c)(1), (2).

piece published in a national newspaper. *Bryant v. Woodall*, 1 F.4th 280, 289 n.2 (4th Cir. 2021).

The parties do not dispute the authenticity of the documents filed with the Motion to Dismiss and the brief in opposition thereto, although they offer different interpretations of some of the documents. I find it appropriate to take judicial notice of the fact of the issuance of Release No. 172, the various forms and drug lists, and the Medicaid Memo. I will consider these documents without converting the Motion to Dismiss into a motion for summary judgment pursuant to Federal Rule of Civil Procedure 12(d).

III.

When deciding a motion to dismiss under Federal Rule of Civil Procedure 12(b)(6), the court's "inquiry is to determine whether the facts alleged in the plaintiff's complaint are legally sufficient to state a claim upon which relief can be granted." *Fessler v. IBM Corp.*, 959 F.3d 146, 151–52 (4th Cir. 2020). "Because only the legal sufficiency of the complaint, and not the facts in support of it, are tested under a Rule 12(b)(6) motion, [the court] assume[s] the truth of all facts alleged in the complaint and the existence of any fact that can be proved, consistent with the complaint's allegations." *Id.* at 152 (citation omitted). "To survive a motion to dismiss, [the court] require[s] 'only enough facts to state a claim to relief

that is plausible on its face.'" *Id*. (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)).

Claims brought under the FCA and other anti-fraud statutes must be pled with the heightened particularity required by Rule 9(b) of the Federal Rules of Civil Procedure. *Smith v. Clark/Smoot/Russell*, 796 F.3d 424, 432 (4th Cir. 2015). To satisfy Rule 9(b), a plaintiff must plead "the time, place, and contents of the false representations, as well as the identity of the person making the misrepresentation and what he obtained thereby." *Harrison v. Westinghouse Savannah River Co.*, 176 F.3d 776, 784 (4th Cir. 1999) (citation omitted). Fraudulent "intent . . . may be alleged generally." Fed. R. Civ. P. 9(b). A fraud claim likely passes muster under Rule 9(b) "if the court is satisfied (1) that the defendant has been made aware of the particular circumstances for which [it] will have to prepare a defense at trial, and (2) that plaintiff has substantial prediscovery evidence of those facts." *Harrison*, 176 F.3d at 784.

Some courts have held that allegations on "information and belief" do not satisfy Rule 9(b)'s heightened pleading standard except where the allegations relate to facts solely within the knowledge of the opposing party. *Sestra Sys., Inc. v. BarTrack, Inc.*, 2020 WL 7212581, at *7 (W.D. Va. Dec. 7, 2020); s*ee also United States ex rel. Cimino v. IBM Corp.*, 3 F.4th 412, 424 (D.C. Cir. 2021) ("Although a relator may plead allegations upon 'information and belief,' he may

do so only when 'the necessary information lies within the defendant's control,' and the allegations are 'accompanied by a statement of the facts upon which the allegations are based.'") (citation omitted).

A. Counts I and II — Direct FCA Claims.

Count I asserts a claim of Making a False Claim under the FCA, 31 U.S.C. § 3729(a)(1)(A). That subsection makes liable a person who "knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval." *Id.* "Knowingly" is defined to mean that the person making the fraudulent claim "has actual knowledge of the information," "acts in deliberate ignorance of the truth or falsity of the information," or "acts in reckless disregard of the truth or falsity of the information." 31 U.S.C. § 3729(b)(1)(A). "[N]o proof of specific intent to defraud" need be shown. 31 U.S.C. § 3729(b)(1)(B).

Count II is a claim of Knowingly Making or Using a False or Fraudulent Record Material to a False or Fraudulent Claim in violation of the FCA, 31 U.S.C. § 3729(a)(1)(B). That subsection of the FCA makes liable a person who "knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim." *Id.* In their briefs, the parties do not distinguish between Counts I and II; they refer to both as direct FCA claims and appear to argue the same points as to both counts.

A person can only be held liable under the FCA for a false statement that is material, *Universal Health Servs., Inc. v. United States ex rel. Escobar*, 579 U.S. 176, 192 (2016), which is defined as "having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property," 31 U.S.C. § 3729(b)(4). "[M]ateriality looks to the effect on the likely or actual behavior of the recipient of the alleged misrepresentation." *Universal Health Servs., Inc.* 579 U.S. at 193 (internal quotation marks, citation, and alterations omitted). The FCA's materiality standard is "demanding." *Id.* at 194. "[P]roof of materiality can include, but is not necessarily limited to, evidence that the defendant knows that the Government consistently refuses to pay claims in the mine run of cases based on noncompliance with the particular statutory, regulatory, or contractual requirement." *Id.* at 194–95.

Walgreens' argument as to all counts in this case is that Virginia Medicaid's preauthorization requirements for the relevant drugs were contrary to federal law. With respect to Count I, Walgreens argues that Reilly's false statements to DMAS and its agents could not have been material because DMAS was legally obligated to pay the claims for the relevant drugs for Patients 1 through 12 regardless of the patients' disease severity or use of illicit substances. Walgreens acknowledges that this argument is a novel one. It can point to no similar case because, it represents,

the government has never before tried to use an FCA claim to enforce unenforceable payment criteria.

The plaintiffs respond that Walgreens cannot collaterally attack the validity of the prior authorization criteria in this FCA suit. They argue that the prior authorization criteria were presumptively lawful, as they were never challenged and invalidated while they were in effect. They contend that Section 1927 of the Social Security Act refers only to excluding a drug from a formulary altogether, which Virginia Medicaid did not do here.

I agree with Walgreens that the prior authorization criteria at issue here were in contravention of the governing federal statute. The portion of Section 1927 addressing "[l]imitations on coverage of drugs" that sets forth "permissible restrictions" provides that "[a] State may exclude or otherwise restrict coverage of a covered outpatient drug if --

> (i) the prescribed use is not for a medically accepted indication (as defined in subsection (k)(6));
>
> (ii) the drug is contained in the list referred to in paragraph (2);
>
> (iii) the drug is subject to such restrictions pursuant to an agreement between a manufacturer and a State authorized by the Secretary under subsection (a)(1) or in effect pursuant to subsection (a)(4); or
>
> (iv) the State has excluded coverage of the drug from its formulary established in accordance with paragraph (4).

42 U.S.C. § 1396r-8(d)(1)(B). None of these four enumerated scenarios apply to Virginia Medicaid's treatment of the relevant drugs. The statute contains no exception for very expensive drugs. Cost is not a permissible reason for a state to limit access to a medically necessary drug.

The plaintiffs characterize Walgreens' position as collaterally attacking the preauthorization requirements, but the plaintiffs are required to plead facts that plausibly show that the submitted false statements and records were material to the payment decision. While the parties agree that CMS's Release 172 was merely agency guidance and does not have the effect of law, it does present a compelling interpretation of the applicable statute. The plaintiffs are correct that Release 172 does not plainly state that the referenced prior authorization criteria are illegal, but that is certainly what it implies, and that implication aligns with the statute.

In oral argument, for the first time, the plaintiffs argued that the portion of Section 1927 cited by Walgreens only addresses a state's wholesale exclusion of a drug from its formulary. The plaintiffs contend that provision does not apply to the situation presented in this case, where the relevant drugs were covered for some individuals who met preauthorization criteria.

This argument misses the mark because it addresses only one subsection of the statute. The portion of the statute addressing formularies provides, in relevant part, that states providing Medicaid drug coverage may only exclude a drug from

coverage "with respect to the treatment of a specific disease or condition for an identified population (if any)" if "the excluded drug does not have a significant, clinically meaningful therapeutic advantage in terms of safety, effectiveness, or clinical outcome of such treatment for such population over other drugs included in the formulary and there is a written explanation (available to the public) of the basis for the exclusion." 42 U.S.C.A. § 1396r-8(d)(4)(C). This is the subsection to which Walgreens pointed during oral argument to support its position, following CMS's lead in Release 172.

If, as the plaintiffs argue, subsection (d)(4)(C) does not govern Virginia Medicaid's restrictions on coverage of the relevant drugs, then Virginia's prior authorization requirements must fit into one of the other enumerated exceptions in subsection (d)(1)(B), which addresses limitations on coverage. The plaintiffs have offered no interpretation of that plainly applicable subsection that would have allowed the restrictions at issue here. They do not contend that the restrictions fit within subparagraphs (i), (ii) or (iii) of § 1396r-8(d)(1)(B). Their conclusory argument that Virginia Medicaid's preauthorization requirements were valid is unpersuasive.

Virginia Medicaid excluded the relevant drugs from coverage for an entire population — those recipients who did not meet the seemingly arbitrary and cost-based disease severity and substance use requirements. While the federal

Medicaid statute does allow states to require "the approval of the drug before its dispensing for any medically accepted indication," 42 U.S.C. § 1396r-8(d)(5), with respect to the relevant drugs, prior authorization was not based on any individualized assessment or a physician's opinion as to medical necessity. The physicians prescribing the drugs had presumably concluded that the drugs were medically necessary for the patients. Despite this necessity, the relevant drugs were not covered for these patients. One can reasonably infer from the Complaint's allegations that there was nothing a patient's doctor could do to convince DMAS and its contractors to cover the drugs for a particular patient for whom the drugs were medically necessary, even though there was no equally effective alternative treatment. If the patient had a metavir score of F2 or below, a fibrosis score less than 0.59, or a recent history of drug or alcohol use, the relevant drugs would not be covered regardless of the patient's need for them. The prior authorization criteria therefore went beyond a simple system for preapproval and served as a mechanism for improperly limiting or excluding coverage in violation of Section 1927.

In *B.E. v. Teeter*, No. C16-227-JCC, 2016 WL 3033500 (W.D. Wash. May 27, 2016), the court found that nearly identical preauthorization requirements for Washington Medicaid enrollees contravened federal law and were unenforceable. In that case, the plaintiff enrollees filed suit under 42 U.S.C. § 1983 against the

state agency that administered the Medicaid program and sought to enjoin the agency from restricting access to the relevant drugs based on fibrosis score. *Id.* at *1. From the evidence presented, the court concluded that the relevant drugs were medically necessary for all patients with hepatitis C regardless of fibrosis score. *Id.* at *2. The court held that the state's policy denying coverage of these medically necessary drugs to patients with fibrosis scores less than F3 violated 42 U.S.C. § 1396a(a)(10)(A). *Id.* (citing *Alvarez v. Betlach*, 572 F. App'x 519, 520–21 (9th Cir. 2014) (unpublished)). Although the *B.E.* court relied on a different section of the Social Security Act, the reasoning is the same: states that opt to provide coverage of certain drugs under their Medicaid plans must provide that coverage when the drugs in question are medically necessary.

For purposes of the Motion to Dismiss, the ultimate question is whether the plaintiffs have adequately pled that the falsified documents purporting to show satisfaction of the invalid prior authorization criteria were material to the payment decisions. On a superficial level, the fraudulent statements and records did influence the decision of DMAS and its contractors to approve reimbursement for the relevant drugs. But the falsified records *should not have* so influenced the decision-making because the drugs should have been covered for Patients 1 through 12 regardless of the information contained on the falsified records. The relevant drugs should have been covered because they were properly prescribed

medically necessary treatments for which there was not an equally effective covered alternative. The plaintiffs have not alleged that the drugs were not medically necessary for Patients 1 through 12 or that there were equally effective alternative medications that would have been covered.

Reilly's dishonesty and misconduct are regrettable, to say the least, and it certainly should not be rewarded. But the reality is that the Complaint's allegations show that Walgreens received payment for medications that had been properly prescribed to Virginia Medicaid enrollees with hepatitis C, who actually received that medication, for which Walgreens was entitled to be reimbursed by Virginia Medicaid under the federal statute governing Medicaid funds. The allegations reveal that Walgreens did not receive any payment that it was not entitled to receive. Given the plain text of 42 U.S.C. § 1396r-8(d)(1)(B), the plaintiffs have not plausibly pled that the falsified documents were material. Because the FCA theories set forth in Counts I and II both require materiality, those counts must be dismissed.

B. Counts IV and V — Direct VFATA Claims.

Count IV asserts a claim under VFATA for Making a False Claim in violation of Va. Code Ann. § 8.01-216.3(A)(1) (Supp. 2021). This subsection of the Virginia statute makes liable a person who "[k]nowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval." *Id.* Count V is

a claim of Knowingly Making or Using a False or Fraudulent Record Material to a False or Fraudulent Claim, in violation of VFATA, Va. Code Ann. § 8.01-216.3(A)(2) (Supp. 2021). This subsection of VFATA makes liable a person who "[k]nowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim." *Id.* VFATA defines "material" as "having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property." Va. Code Ann. § 8.01-216.2 (2015).

These claims are essentially the same as Counts I and II, and the parties make the same arguments here. VFATA's requirements are virtually identical to those of the FCA. The plaintiffs' VFATA claims fail for the same reasons as their direct FCA claims. Counts IV and V will be dismissed for failure to state plausible claims for relief because the falsified records, which purported to show satisfaction of the invalid prior authorization criteria, could not have been material.

C. Counts III and IV — Reverse False Claims (FCA and VFATA).

Count III alleges a Reverse False Claims theory under the FCA, 31 U.S.C. § 3729(a)(1)(G). That subsection, in relevant part, makes liable a person who "knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the Government." *Id.* "[T]he term 'knowingly' must be interpreted to refer to a defendant's awareness of *both* an obligation to the United States *and* his violation of that obligation." *United*

States ex rel. Harper v. Muskingum Watershed Conservancy Dist., 842 F.3d 430, 436 (6th Cir. 2016).

The FCA defines an "obligation" as "an established duty, whether or not fixed, arising from an express or implied contractual, grantor-grantee, or licensor-licensee relationship, from a fee-based or similar relationship, from statute or regulation, or from the retention of any overpayment." 31 U.S.C. § 3729(b)(3). The Patient Protection and Affordable Care Act ("PPACA") defines a Medicaid overpayment as "any funds that a person receives or retains under [the Medicaid statutes] to which the person, after applicable reconciliation, is not entitled under [the Medicaid statutes]." 42 U.S.C. § 1320a-7k(d)(4)(B). The PPACA requires a recipient to return an overpayment within 60 days of when it is identified; if the overpayment is not timely returned, an obligation arises under the FCA. 42 U.S.C. § 1320a-7k(2), (3). At least one court has held that an overpayment is identified "when a provider is put on notice of a potential overpayment." *Kane ex rel. United States v. Healthfirst, Inc.*, 120 F. Supp 3d 370, 388 (S.D.N.Y. 2015). The same court held that "the plain meaning of 'avoid' includes behavior where an individual is put on notice of a potential issue, is legally obligated to address it, and does nothing." *Id.* at 394.

Walgreens argues that there was no overpayment for it to have identified because Patients 1 through 12 were entitled to coverage for the relevant drugs even

without considering the falsified documents. Similarly, it argues it did not improperly avoid repaying the government, and had no obligation to repay the funds, because there was a good faith dispute over whether Virginia Medicaid's prior authorization criteria were lawful.

The Chamber of Commerce of the United States of America ("Chamber") has filed an amicus brief in support of Walgreens' position in which it argues that the plaintiffs essentially seek to turn the reverse FCA provision into a strict liability statute. The Chamber contends that the Complaint's allegations are inadequate as to Count III because it does not allege that either Walgreens itself or any administrative or judicial body ever determined that Walgreens had in fact received an overpayment. According to the Chamber,

> As pleaded, the government's theory amounts to the assertion that if the government tells a company that *the government believes* it is owed money, the company is required to take the government's word for it and immediately meet the government's payment demand or face crushing treble damages and penalties for violating the False Claims Act.

Amicus Br. 2, ECF No. 23.

As to the reverse false claim counts, the plaintiffs must plead that (1) Walgreens had an obligation to repay the government, (2) it improperly avoided repaying the funds, and (3) it did so knowingly. *Muskingum Watershed Conservancy Dist.*, 842 F.3d at 436. The alleged obligation is based on failure to

return a Medicaid overpayment within 60 days of identification, as set forth in the PPACA.

As discussed in Part II.A, supra, there was no overpayment here. Walgreens received payments that it was entitled to receive under federal law, for dispensing properly prescribed drugs that were medically necessary for the patients who received them. Because there was no overpayment, the failure to repay the funds within 60 days did not give rise to any obligation. The plaintiffs have thus failed to state a plausible claim for relief under a reverse false claims theory.

Count VI asserts a theory of Reverse False Claims under VFATA, Va. Code Ann. § 8.01-216.3(A)(8) (Supp. 2021). This subsection renders liable a person who "[k]nowingly makes, uses, or causes to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the Commonwealth or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the Commonwealth." *Id.* VFATA defines "obligation" as "an established duty, whether or not fixed, arising from (i) an express or implied contractual, grantor-grantee, or licensor-licensee relationship; (ii) a fee-based or similar relationship; (iii) a statute or regulation; or (iv) the retention of any overpayment." Va. Code Ann. § 8.01-216.2 (2018).

The parties' arguments with respect to Count VI are the same as those with respect to Count III, the reverse false claim count under the FCA. The statutory provisions are virtually identical. Count IV, therefore, must also be dismissed, as the allegations fail to show any overpayment or corresponding obligation to repay funds for purposes of VFATA.

D. Count VII.

In Count VII, the plaintiffs contend that Walgreens violated the Virginia Medicaid Fraud Statute, Va. Code Ann. § 32.1-312 (2018). That statute states, in relevant part:

> A. No person, agency or institution, . . . shall obtain or attempt to obtain benefits or payments where the Commonwealth directly or indirectly provides any portion of the benefits or payments pursuant to the Plan for Medical Assistance and any amendments thereto as provided for in § 32.1-325, hereafter referred to as "medical assistance" in a greater amount than that to which entitled by:
>
> 1. Knowingly and willfully making or causing to be made any false statement or false representation of material fact; [or]
>
> 2. Knowingly and willfully concealing or causing to be concealed any material facts[.]

Id.

For our purposes, the key phrase in the statute is "in a greater amount than that to which entitled." *Id.* Again, the amounts that Walgreens allegedly received were amounts to which it was entitled under the federal law. It therefore cannot be liable under the Virginia Medicaid Fraud Statute, and I will dismiss Count VII.

E. Counts VIII and IX.

Count VIII is a common law unjust enrichment claim. Under Virginia law, a party claiming unjust enrichment must allege facts showing that: (1) the plaintiff conferred a benefit on the defendant; (2) the defendant "knew of the benefit and should reasonably have expected to repay" the plaintiff; and (3) the defendant "accepted or retained the benefit without paying for its value." *Schmidt v. Household Fin. Corp., II*, 661 S.E.2d 834, 838 (Va. 2008).

For the reasons explained above, the allegations do not show that Walgreens should reasonably have expected to repay the plaintiffs the funds received for dispensing the relevant drugs to Patients 1 through 12. I will therefore dismiss Count VIII.

Count IX is a claim of payment by mistake. Under Virginia law, "a right of recovery . . . in the case of money paid by mistake of fact" is based on an implied promise to return the money "whenever the circumstances are such that ex æquo et bono the money should be paid back." *Hibbs v. First Nat'l Bank of Alexandria*, 112 S.E. 669, 673 (Va. 1922). "[P]ayment or overpayment under a mistake of fact" is a form of unjust enrichment. *James G. Davis Constr. Corp. v. FTJ, Inc.*, 841 S.E.2d 642, 647 (Va. 2020). Count IX must be dismissed for the same reason as Count VIII. The mistaken facts were not material and the circumstances are not such that the money should be repaid.

F. Count X.

Count X is a common law fraud claim. "Common law fraud consists of (1) a false representation, (2) of a material fact, (3) made intentionally and knowingly, (4) with intent to mislead, (5) reliance thereon by the party misled, and (6) resulting damage to the party misled." *Owens v. DRS Auto. Fantomworks, Inc.*, 764 S.E.2d 256, 260 (Va. 2014). The lack of materiality dooms this claim, along with a lack of resulting damage, given that the plaintiffs were obligated to pay the patients' claims for the relevant drugs. Count X will be dismissed as well.

IV.

For the foregoing reasons, it is **ORDERED** that the Motion to Dismiss, ECF No. 8, is GRANTED. A separate judgment will be entered herewith.

ENTER: December 2, 2021

/s/ JAMES P. JONES
Senior United States District Judge