

Following the hearing, the parties submitted post-hearing briefs and proposed findings of facts and conclusions of law on April 28, 2022, as well as supplemental material requested by the Court regarding the amount of the claims in issue on May 24, 2022, whereupon the record closed.

After careful consideration of the evidence and the parties' arguments, and for the reasons stated below, the Department's decision to seek recoupment with respect to the Claims at issue is **REVERSED**.

II. OVERVIEW

This case turns upon the proper interpretation of Georgia Board of Pharmacy regulation 480-27-.05(a), referred to in this Decision as the "Original Prescription Requirement." The Original Prescription Requirement, which has been incorporated into Medicaid program rules by the Department, obligates Georgia-licensed pharmacy providers to maintain copies of "all original prescriptions" — whether hard copy, telephoned-in, faxed, or electronic — to support claims for prescription drug dispensations billed to the Georgia Medicaid Program.¹

In this case, the Department argues that Walgreens failed to maintain the "original prescription record" underlying the Claims previously reimbursed by the Georgia Medicaid Program. The Department seeks to recoup amounts paid with respect to those Claims. As will be discussed below, the Department's position fails for three reasons.

First, certain of the Claims involve records of technical updates to a previously issued, already authorized original prescription. These technical updates do not require subsequent authorization (or reauthorization) by the prescriber and, therefore, do not result in, or require, a new prescription. Instead, updates to the original prescription are noted in Walgreens' proprietary

¹ See Ga. Comp. R. & Regs. 480-27-.05(a) (requiring retention of "original prescriptions"); O.C.G.A. § 26-4-80(e) (governing documentation requirements for subsequently authorized refills); Pharmacy Services Manual § 603 (requiring "original documentation" of prescription drug order information, consistent with Pharmacy Board Rules).

electronic prescription fulfillment and recordkeeping system, utilizing an electronic documentation functionality known as “Copy/Create.” The Department’s pre-hearing briefing did not address these types of records.

Second, certain of the Claims involve records of changes to the original prescription that do require subsequent prescriber authorization, but which do not create a brand-new original prescription. Georgia law requires that subsequent refill authorizations be recorded either on the original prescription record “or on some other uniformly maintained record.”² The statute itself contemplates that authorized refill events are not themselves new original prescriptions, but merely annotations to already existing original prescriptions. Walgreens’ Copy/Create documentation functionality records these refill authorizations in a “uniformly maintained record,” — and thus satisfies Georgia law.³

Finally, even if the Copy/Created records at issue are viewed as standalone original prescriptions, the information stored in the Copy/Created record satisfies the Original Prescription Requirement by itself.

III. FINDINGS OF FACT⁴

A. Intercom Plus

1. Walgreens uses a proprietary electronic prescription fulfillment and recordkeeping system called Intercom Plus to record and store prescription drug orders and to record specific

² See O.C.G.A. § 26-4-80(e); Ga. Comp. R. & Regs. 480-27-.05(a).

³ See *id.*

⁴ Citations to Findings of Fact are to the official recording made by the Office of State Administrative Hearings of the hearing in this case, which took place on March 7, 2022 (herein, “Hr’g Recording”), with pincites provided in Hours:Minutes:Seconds format.

information about individual dispensations of prescription drugs. Hr'g Recording, at 03:07:27 – 03:08:24 (Testimony of J. Arends).

2. Intercom Plus stores both original prescription drug orders and other records related to those original prescription drug orders. *See, e.g., id.* at 03:08:55 – 03:09:01, 03:10:47 – 03:11:09 (Testimony of J. Arends.).

3. Walgreens maintains these documents and information within Intercom Plus (and its associated data warehouse) for at least 10 years, including original prescription drug orders and subsequent dispensation records. *Id.* at 03:08:25 – 03:08:54 (Testimony of J. Arends.).

4. Individual Walgreens pharmacy locations can access original prescription records, and other records related to original prescriptions, through Intercom Plus at each Walgreens branch location. *Id.* at 03:39:20 – 03:39:40, 03:40:37 – 03:41:55 (Testimony of J. Arends.).

5. In keeping with the ever-increasing digitization of data generally, and in the pharmacy industry specifically, electronic recordkeeping systems similar to Intercom Plus are used by pharmacies throughout the industry. *See id.* at 04:25:20 – 04:27:08, 04:13:08 – 04:13:49 (Testimony of M. Oppong).

B. Original Prescription Drug Orders

1. Valid prescription drug orders can be received by a Walgreens pharmacy via hard copy, fax, telephone, or electronic transmission. *Id.* at 02:57:18 – 02:57:44 (Testimony of J. Arends.); *accord* 04:11:10 – 04:11:18 (Testimony of M. Oppong.); 00:43:38 – 00:44:12 (Testimony of M. Reed.); 02:35:34 – 02:36:00 (Testimony of P. D'Alba.).

2. Prescription drug orders are entered into and stored in Intercom Plus in different ways, depending on how Walgreens receives them. *See id.* at 03:09:02 – 03:10:37 (Testimony of J. Arends.).

3. Hard copy orders are scanned. The image is saved, and the order information is transcribed by the pharmacist into Intercom Plus. *Id.* at 03:09:20 – 03:09:42, 03:41:25 – 03:41:33 (Testimony of J. Arends.).

4. Faxed orders are scanned. The image is saved, and the order information is transcribed by the pharmacist into Intercom Plus. *Id.* at 03:41:34 - 03:41:38 (Testimony of J. Arends.).

5. Electronic orders are received via electronic file transmitted through an independent third-party intermediary known as Surescripts, which routes prescribers' prescription drug orders to pharmacies. The Surescripts message ID is retained, and the order information is transformed into sight-readable format and stored in Intercom Plus. *Id.* at 02:58:39 – 03:00:12, 04:00:34 – 04:01:42 (Testimony of J. Arends.).

6. The prescriber's authorization for the prescription drug order is documented differently depending on the format in which the order is conveyed to the pharmacy. *See id.* at 02:58:07 – 03:00:53 (Testimony of J. Arends.).

7. Hard copy orders contain a physical "wet ink" signature by the prescriber. *Id.* at 02:58:07 – 02:58:28 (Testimony of J. Arends.); *accord* 04:11:18 – 04:11:40 (Testimony of M. Oppong.).

8. Faxed orders contain a digital image of the prescriber's physical signature. *Id.* at 02:58:28 – 02:58:39 (Testimony of J. Arends.); *accord* 04:12:01 – 04:12:10 (Testimony of M. Oppong.).

9. For electronic orders, Surescripts credentials and validates the identity of the transmitting prescriber and links the prescriber's electronic authorization to the prescription drug

order through the Surescripts message ID. *Id.* at 02:58:39 – 03:00:12 (Testimony of J. Arends.); *accord* 04:12:10 – 04:12:17 (Testimony of M. Oppong.).

10. The prescriber's authorization for telephonic orders is received orally and reduced to writing by a pharmacist or pharmacy technician. *Id.* at 03:00:12 – 03:00:29, 03:09:42 – 03:10:37 (Testimony of J. Arends.); *accord* 04:11:40 – 04:12:01 (Testimony of M. Oppong.).

11. If the pharmacist's or technician's writing is by hand, then the image of the handwritten transcription is scanned and saved, and the order information, including the prescriber's authorization, is transcribed by the pharmacist into Intercom Plus. *Id.* at 03:09:55 – 03:10:15 (Testimony of J. Arends.).

12. If the pharmacist's or technician's writing is electronic (i.e., typed), the writing is entered electronically directly into Intercom Plus. *Id.* at 03:10:15 – 03:10:37 (Testimony of J. Arends.).

13. Pharmacists in the industry regularly use computerized documentation tools to reduce telephonic orders to writing. *See generally id.* at 4:25:20 – 04:27:08 (Testimony of M. Oppong regarding prevalence of computerized documentation tools generally throughout the industry); 04:12:17 – 04:13:08 (Testimony of M. Oppong regarding documentation of telephonic authorization generally); *accord* 03:00:30 – 03:01:44 (Testimony of J. Arends.).

14. Pharmacy practice makes no distinction between a handwritten transcription of an oral prescription drug order and one that is written using the aid of a typewriter or computer. *Id.* at 03:00:28 – 03:01:44 (Testimony of J. Arends.); 04:12:17 – 04:13:08 (Testimony of M. Oppong.).

C. **Copy/Created Records: Additional Records Related to a Prescription Drug Order**

1. After an original prescription drug order is entered, Intercom Plus allows pharmacists to document additional notes, amendments, events, updates, and changes to the order using a functionality called “Copy/Create.” *See id.* at 03:10:47 – 03:12:09 (Testimony of J. Arends.).

2. Copy/Create is a database documentation tool designed to facilitate recordkeeping within Intercom Plus. *Id.* at 03:02:52 – 03:03:38, 03:10:47 – 03:11:09 (Testimony of J. Arends.); *accord* 04:25:19 – 04:26:19 (Testimony of M. Oppong.).

3. The Copy/Create function copies the prescription order information from the original prescription record into a supplemental database record and allows the pharmacist to document appropriate updates, notes, changes, or other events in the new record (for the applicable drug dispensation) without overwriting the original prescription record itself. *See, e.g., id.* at 03:02:52 – 03:04:38; 03:10:47 – 03:11:09 (Testimony of J. Arends.); *accord* 04:24:40 – 04:25:19 (Testimony of M. Oppong.).

4. Pharmacists may use Copy/Create for a variety of reasons, including to document the following types of common “events” in the life of a prescription:

- a. Recording additional refill authorizations for a prescription that no longer has any fills or refills available (*id.* at 03:05:09 – 03:05:27, 03:14:54 – 03:15:27 (Testimony of J. Arends.));
- b. Updating the manufacturer of a generic medication being dispensed (and updating the drug’s National Drug Code, or “NDC,” accordingly) (*id.* at 03:03:38 – 03:04:38 (Testimony of J. Arends.));

- c. Changing the dispensing pharmacy address of record (i.e., in the case of a prescription transfer to a different pharmacy location) (*id.* at 03:05:33 – 03:06:13 (Testimony of J. Arends.));
- d. Recording the filling of a prescription drug order that was previously brought to the pharmacy and stored on-file, but which was not filled at that time. When drugs authorized by the stored prescription are dispensed at a later date, the pharmacist uses Copy/Create to document the dispensation (known as a “store and fill later” event) (*id.* at 03:06:13 – 03:07:07 (Testimony of J. Arends.));
- e. Updating a prescriber’s authorization for an existing prescription that was written more than one year earlier (*id.* at 03:04:52 – 03:05:09, 03:11:17 – 03:11:33 (Testimony of J. Arends.));
- f. Various other administrative tasks related to an existing prescription including, for example, to resolve certain technical system issues that impede submission of claims for reimbursement, or to resolve other operational issues that do not involve subsequent prescriber authorization or a change to the prescription drug order itself (*id.* at 03:11:33 – 03:12:09, 03:13:47 – 03:14:20 (Testimony of J. Arends.)).

5. Copy/Created records are not pharmacist-created prescription drug orders. Rather, the orders themselves originate with, and are generated and authorized by, prescribers. Copy/Create is the documentation tool used by pharmacists to record certain prescription drug order and dispensation information. *See id.* at 03:44:16 – 03:44:44 (Testimony of J. Arends.); 04:15:52 – 04:16:07, 04:27:30 – 04:28:20 (Testimony of M. Oppong.).

6. Many events in the life of a prescription that may result in the creation of Copy/Created records do not require or involve any prescriber authorization subsequent to the original prescription drug order itself. *Id.* at 03:11:09 – 03:12:09, 03:14:38 – 03:14:54 (Testimony of J. Arends.); *see also, e.g.*, 04:36:04 – 04:37:20 (Testimony of M. Oppong); *accord* 01:30:28 – 01:30:45, 01:31:29 – 01:31:49 (Testimony of M. Reed.).

7. Such Copy/Created records do not include any evidence of subsequent prescriber authorization, as none is required and none exists. *Id.* at 03:13:18 – 03:13:34 (Testimony of J. Arends.); *see also, e.g.*, 04:36:04 – 04:37:20 (Testimony of M. Oppong).

8. Indeed, many Copy/Created records do not involve any change at all to the existing prescription drug order, and therefore do not include documentation of prescriber authorization. *Id.* at 03:07:08 – 03:07:17, 03:13:47 – 03:14:20 (Testimony of J. Arends.); *see also, e.g.*, 04:14:16 – 04:15:48, 04:37:20 – 04:37:59 (Testimony of M. Oppong); *see also* 01:31:29 – 01:32:49 (Testimony of M. Reed.).

9. The following types of prescription events are within a pharmacist's scope of practice and do not require express prescriber authorization ("Non-Authorization Events"):

- a. Change of drug manufacturer (*see id.* at 03:03:38 – 03:04:08 (Testimony of J. Arends.); 00:47:25 – 00:47:41 (Testimony of M. Reed.));
- b. Store and fill later event (*id.* at 03:06:13 – 03:07:07 (Testimony of J. Arends.); 04:14:16 – 04:15:48 (Testimony of M. Oppong.); *accord* 00:47:54 – 00:48:12, 01:31:29 – 01:31:49 (Testimony of M. Reed.));
- c. Change of pharmacy address in the case of a prescription transfer (*id.* at 03:05:28 – 03:06:13 (Testimony of J. Arends.); *accord* 00:47:44 – 00:47:54 (Testimony of M. Reed.));

- d. Adjustment to dispense less than the total authorized quantity of a prescription medication, or to dispense in smaller batches (*id.* at 02:38:44 – 02:39:00 (Testimony of P. D’Alba.);
- e. Annotations made at pharmacist’s discretion, e.g., to clarify some aspect of the prescription drug order for the avoidance of confusion or to document some relevant fact relating to a particular dispensation (*see, e.g., id.* at 03:23:07 – 03:23:42 (Testimony of J. Arends.)).

10. It is undisputed that pharmacists have discretion, within their state-licensed scope of practice, to make notes and record such Non-Authorization Events as may occur during the life of an existing prescription drug order, and to document such events in updated dispensing records associated with a patient’s existing prescription. *See, e.g., id.* at 03:01:45 – 03:04:38 (Testimony of J. Arends.); 04:14:16 – 04:15:48 (Testimony of M. Oppong.); *accord* 01:30:28 – 01:30:45, 01:31:49 – 01:32:49 (Testimony of M. Reed.); 02:39:07 – 02:39:47 (Testimony of P. D’Alba.).

11. Other events documented using Copy/Create require express prescriber authorization (“Authorization Events”), including a prescriber’s authorization of additional refills on an existing prescription. *Id.* at 03:14:54 – 03:15:27 (Testimony of J. Arends.); 04:16:08 – 04:16:40 (Testimony of M. Oppong.).

12. If subsequent prescriber authorization is required for the Copy/Create event itself (as discussed above), that authorization is documented in the Copy/Create record according to the manner in which that authorization was provided by the prescriber. *See id.* at 02:58:07 – 03:00:53 (Testimony of J. Arends); *accord* 04:11:10 – 04:12:17 (Testimony of M. Oppong.).

13. Where the prescriber's authorization is provided telephonically, the pharmacist reduces that authorization to writing within the Copy/Created record. *See, e.g., id.* at 03:26:30 – 03:32:01, 03:52:00 – 03:54:15, 03:00:12 – 03:01:44 (Testimony of J. Arends).

14. It is Walgreens' policy to obtain and document prescriber authorization for all events that require or involve prescriber authorization prior dispensing a drug to a patient. *Id.* at 03:14:54 – 03:15:27 (Testimony of J. Arends.); *accord* 04:32:29 – 04:32:42 (Testimony of M. Oppong.).

15. Copy/Created records are tied to the prescription drug orders to which they relate within the Intercom Plus system. *Id.* at 03:12:09 – 03:12:30, 03:57:47 – 03:58:00 (Testimony of J. Arends.); *see also, e.g.,* 04:36:04 – 04:37:20 (Testimony of M. Oppong).

16. Although the Copy/Created record is assigned a new prescription number within Intercom Plus for internal recordkeeping purposes, the Copy/Created record specifically refers back to the original prescription record (by prescription number) and is electronically associated with the original prescription drug order to which it relates. *Id.* at 03:12:09 – 03:12:30 (Testimony of J. Arends.); *see also, e.g.,* 04:36:41 – 04:37:20 (Testimony of M. Oppong).

17. The assignment of a new prescription number for Copy/Created records allows records to be uniquely and easily identified, which ensures that Copy/Created records remain attached to both the specific prescription drug dispensation and the original prescription drug order to which it relates. Use of a new prescription number does not, standing alone, create a new prescription. *See id.* at 03:03:01 – 03:04:38, 03:38:05 – 03:08:45, 03:39:40 – 03:40:36 (Testimony of J. Arends.); *see also* 04:37:20 – 04:37:59 (Testimony of M. Oppong).

18. Individual Walgreens branch locations can access and produce the Copy/Created records associated with an individual prescription dispensation, along with the original

prescription record of the original prescription drug order. *Id.* at 03:39:20 – 03:39:40, 03:40:37 – 03:41:55 (Testimony of J. Arends.).

19. Electronic documentation tools and functionalities that are materially similar to Copy/Create are used by pharmacists and pharmacies throughout the pharmacy industry. *Id.* at 04:25:19 – 04:26:19 (Testimony of M. Oppong.).

20. Such documentation tools are crucial to the efficient and consistent operation of pharmacies that use electronic prescription fulfillment and recordkeeping systems (as almost all pharmacies now do). *Id.* at 04:26:02 – 04:26:19 (Testimony of M. Oppong.).

21. Using Copy/Create, or a similar functionality, ensures that prescription records are consistently and securely maintained, accurately documented, and can be reliably accessed. *Id.* at 04:25:36 – 04:26:02 (Testimony of M. Oppong.).

22. The Copy/Create functionality is more reliable than physically attaching notes, documents, or records to hard copy prescription drug orders, as Copy/Create ensures that records remain associated with the prescription drug orders to which they relate. *Id.* at 04:21:04 - 04:22:05 (Testimony of M. Oppong.); *see also, e.g.*, 03:03:38 – 03:04:38 (Testimony of J. Arends.).

D. This Dispute

1. This case involves 91 prescription drug claims for which Walgreens received reimbursement from the Georgia Medicaid program. *Id.* at 03:19:21 – 03:19:29 (Testimony of J. Arends.); *accord* 00:44:49 – 00:45:55 (Testimony of M. Reed.).

2. None of the Claims involve prescriptions for drugs that are classified as controlled substances. *Id.* at 02:49:19 – 02:49:25 (Testimony of P. D’Alba.); 04:18:26 – 04:18:34 (Testimony of M. Oppong.).

3. For each of the Claims, Walgreens provided at least one Copy/Created record as well as documentation of the original, first-in-time prescription to which the Copy/Created record

relates. *See, e.g., id.* at 03:12:30 – 03:12:55, 03:16:50 – 03:18:55, 03:41:11 – 03:42:11 (Testimony of J. Arends.); 04:23:49 – 04:24:30 (Testimony of M. Oppong.); 00:50:41 – 00: 51:18, 01:20:03 – 01:20:31 (Testimony of M. Reed acknowledging that both Copy/Created records and documentation of a prescription supporting a prior fill was provided for each of the 91 Claims).

4. The Claims can be grouped into two categories: 1) those involving Copy/Created records that memorialize Authorization Events; and 2) those involving Copy/Created records that memorialize Non-Authorization Events. Hr’g Recording at 03:34:19 – 03:35:00 (Testimony of J. Arends.).

5. The 18 records behind Tab A of Petitioner’s Exhibit 1 involve Authorization Events. Hr’g Recording at 03:34:19 – 03:35:00 (Testimony of J. Arends.).

6. The 73 records behind Tab B of Petitioner’s Exhibit 1 involve Non-Authorization Events. *See* Hr’g Recording at 03:34:19 – 03:35:00 (Testimony of J. Arends.).

7. All Authorization Events memorialize the authorization of additional dispensations (refills) of a prescription drug, beyond those that were initially authorized by the original prescription drug order. *See* Pet’r’s Ex. 1, Tab A.

8. The vast majority of all Authorization Events at issue reflect telephonic authorization for the additional refills that was reduced to writing by a pharmacist. *See* Pet’r’s Ex. 1, Tab A.

9. Copy/Created records show that the pharmacist reduced the telephonic authorization to writing using the Copy/Create functionality. *See, e.g.,* Hr’g Recording at 03:26:30 – 03:32:01, 03:52:00 – 03:54:15 (Testimony of J. Arends regarding typewritten annotations of telephone authorizations for Claims 10 and 1).

10. Copy/Created records memorializing an Authorization Event include the requisite elements of a valid prescription drug order — even without reference to the original prescription record. *See, e.g., id.* at 03:16:35 – 03:16:48, 04:38:11 – 04:38:42 (Testimony by each of J. Arends and M. Oppong that Copy/Created records are capable of documenting all requisite elements of a valid prescription drug order and complying with the Original Prescription Requirement); 03:25:24 – 03:29:59, 03:32:37 – 03:32:53, 4:32:57 – 04:33:26 (Testimony by each of J. Arends and M. Oppong identifying all requisite elements of a valid prescription drug order in the Copy/Create record associated with Claim 10).

11. Copy/Created records memorializing an Authorization Event, including the specific records upon which evidence was presented at the hearing, include a record of that authorization. *See id.* at 03:14:54 – 03:15:27, 03:26:30 – 03:26:59 (Testimony of J. Arends describing the process for documenting prescriber authorization in a Copy/Created record); 03:25:24 – 03:29:59, 03:32:37 – 03:32:53, 4:32:57 – 04:33:26 (Testimony by each of J. Arends and M. Oppong identifying all requisite elements of a valid prescription drug order in the Copy/Create record associated with Claim 10, including documentation of the prescriber’s authorization); 03:30:18 - 03:32:01 (Testimony of J. Arends testimony regarding Claim 1); *see also* Pet’r’s Ex. 1, Claim 1 (Bates 000006 – 000010) and Claim 10 (Bates 000001 – 000005).

12. The Department presented no evidence showing that the prescriber’s authorization was improperly recorded for any of the Copy/Created records memorializing Authorization Events. *See generally* Witness Testimony concerning Claim 1 (Pet’r’s Ex. 1, Bates 000006 – 000010): Hr’g Recording at 00:58:46 – 01:09:36 (M. Reed direct), 01:18:25 – 01:30:20 (M. Reed cross); 01:54:18 – 01:55:10 (M. Reed redirect); 03:30:18 – 03:32:01 (J. Arends direct); Witness Test. concerning Claim 10 (Pet’r’s Ex. 1, Bates 000001 – 000005): Hr’g Recording at 03:21:50 –

03:30:18, 03:32:10 – 03:34:05 (J. Arends direct); 03:52:00 – 03:54:15 (J. Arends cross); 04:01:45 – 04:02:02 (J. Arends redirect); 04:28:22 – 04:33:41 (M. Oppong direct); 04:44:55 – 04:50:35 (M. Oppong cross).

13. Each Copy/Created record memorializing a Non-Authorization Event notes annotations (as if made on a sticky note) to the original prescription to which it relates. *See, e.g., id.* at 03:13:18 – 03:13:47 (Testimony of J. Arends.).

14. Copy/Created records memorializing a Non-Authorization Event, including the specific records upon which evidence was presented at the hearing, are related to an original prescription record that documents all requisite elements of a valid prescription drug order. *See id.* at 03:12:09 – 03:12:30, 03:13:18 – 03:13:34 (Testimony of J. Arends describing the relationship and electronic database linkage between a Copy/Created record of a Non-Authorization Event and the underlying original prescription record); 01:50:31 – 01:51:07 (Testimony of M. Reed acknowledging that the Copy Created record for Claim 22 is linked to the underlying original prescription record); 03:42:15 – 03:43:14 04:33:41 – 04:37:59 (Testimony by each of J. Arends and M. Oppong identifying all requisite elements of a valid prescription drug order on the original prescription record to which the Copy/Created record associated with Claim 22 is linked); *see also* Pet'r's Ex. 1, Claim 22 (Bates 000112 – 000116) and Claim 88 (Bates 000533 – 000537).

15. The Department acknowledges that Georgia allows pharmacies to utilize an automated electronic data processing system to maintain prescription records.⁵ The system must, however, produce a “sight-readable” record for all prescriptions.⁶ “The term ‘sight-readable’ means

⁵ Ga. Comp. R. & Regs. 480-27-.05.

⁶ Ga. Comp. R. & Regs. 480-27-.05(b).

that a representative of the Board [i.e. Georgia State Board of Pharmacy] or GDNA [i.e. Georgia Drugs and Narcotics Agency] must be able to immediately retrieve and examine the record and read the information during any on-site visit to the pharmacy.”⁷ When prescriptions are maintained electronically, the pharmacy’s system must be “capable of printing out or transferring the prescription records in a format that is readily understandable to the representative for the Board or GDNA at the registered location.”⁸ “The computers on which the records are maintained may be located at another location, but the records must be immediately retrievable as hard-copy print-outs or viewing on a computer monitor set aside for such viewing at each individually registered pharmacy upon a verbal request by a representative from the Board or GDNA.”⁹

IV. CONCLUSIONS OF LAW

A. Georgia Law Regarding Medicaid Reimbursement

The Georgia Medicaid Program is administered by the Department. O.C.G.A. § 49-4-142(a); Ga. Comp. R. & Regs. 350-1-.02(2). The Department establishes prescription drug compliance, coverage, and payment rules for the Medicaid Program through its various Policies and Procedures Manuals. *See* Ga. Comp. R. & Regs. 350-1-.02(3). Consistent with the Georgia Medicaid State Plan, prescription drugs eligible for Medicaid reimbursement generally must comply with applicable state laws and regulations of the Georgia State Board of Pharmacy. *See* Pharmacy Services Manual § 603 (“Prescription Requirements”).

⁷ *Id.*

⁸ *Id.* at 480-27.05(b)(2).

⁹ *Id.*

B. Georgia Law Regarding Valid Prescription Drug Orders

Georgia law defines a “prescription drug order” as a “lawful order from a practitioner, acting within the scope of his or her license to practice, for a drug or device for a specific patient.” Ga. Comp. R. & Regs. 480-27-.01(s); *accord* O.C.G.A. § 26-4-5(36). Valid prescription drug orders may be written by the prescribing practitioner, telephoned-in to the pharmacy by the prescriber and reduced to writing by the pharmacist, and/or transmitted electronically or via fax to the pharmacy. Ga. Comp. R. & Regs. 480-27-.01(s); *accord* O.C.G.A. § 26-4-80(c).

Handwritten or hard copy prescriptions must be signed by the prescriber. *See* O.C.G.A. § 26-4-80(i). Telephonic prescription authorizations are not signed by the prescriber, but they must be reduced to writing by the pharmacist receiving the transmission. *See* Ga. Comp. R. & Regs. 480-27-.01(s) (defining a “prescription drug order” as including “a telephone order reduced to writing by the pharmacist”) and 480-10-.09 (upon receipt of telephonic or oral prescription drug order, pharmacists or intern/extern “shall immediately reduce the same to writing”); *accord* Ga. Comp. R. & Regs. 480-27-.05(a) (defining “original prescriptions” as including those “telephoned to the pharmacist by a practitioner and reduced to writing”). “The name of the individual making the transmission and the date, time, and location of the origin of the transmission must be recorded on the original prescription drug order or other record by the pharmacist receiving the transmission.” O.C.G.A. § 26-4-80(i); *see* Pharmacy Services Manual § 603.

Neither the Georgia Pharmacy Practice Act nor the Pharmacy Board Rules expressly define the term “writing.” But it is well-settled under Georgia law generally that “writing” requirements encompass not only handwritten records, but also typewritten and electronic records.¹⁰ Even

¹⁰ *See* O.C.G.A. § 10-12-7(c) (“If a law requires a record to be in writing, an electronic record satisfies the law.”); O.C.G.A. § 44-2-37(a) (“An electronic document prepared and filed in compliance with this part shall satisfy any requirement as a condition for recording that a document be an original, on paper or another tangible medium, or in writing.”); O.C.G.A. § 11-1-201(43) (defining “written” or a “writing” to include “printing, typewriting, or any

absent an express statutory (or regulatory) definition, the Georgia Supreme Court has interpreted the word “writing” broadly enough to include, at a minimum, “a document containing words.” *See Boothe v. State*, 293 Ga. 285, 288-89 (2013) (considering the meaning of a “writing” in the context of Georgia’s former “best evidence” standard, which had lacked an explicit definition of the term). Moreover, the Pharmacy Board Rules distinguish between specific types of writings when the manner of writing is material. *See, e.g.*, Ga. Comp. R. & Regs. 480-22-.03 (listing specific requirements governing prescriptions for controlled substances, specifically addressing “hand written prescription drug order[s]” and those that are “written with ink or indelible pencil, pen, typewriter, or printer”).¹¹

Regardless of the manner in which a prescription order is transmitted, the parties agree that it must contain the following pieces of information: (1) the date the prescription is issued; (2) the patient’s name and address; (3) the prescriber’s name, address, and national provider identification number; (4) the name, strength, dosage form, and quantity of the drug being prescribed; (5) the number of authorized refills, if any; (6) directions for use by the patient; and (7) the prescribing

other intentional reduction to tangible form”); O.C.G.A. § 24-10-1001(1) (defining “writing” or “recording” to include “letters, words, or numbers, or their equivalent, set down by handwriting, typewriting, printing, photostating, magnetic impulse, or mechanical or electronic recording or other form of data compilation”).

¹¹ The Department’s Pharmacy Services Manual ostensibly requires oral prescriptions to be “transcribed to handwritten order.” *See id.* § 603 (also expressly requiring such transcription to comply with Georgia Pharmacy Practice Act § 26-4-80(i)); *see also id.* App’x. J (“Oral prescriptions must have the date, time, name of person calling, and the handwritten initials of the pharmacist/intern who took the call.”). The Georgia Administrative Procedure Act requires all substantive agency rules to undergo notice and comment prior to their adoption. O.C.G.A. § 50-13-4(a)(1). Because the purported handwriting requirement in section 603 of the Department’s Pharmacy Services Manual, if taken literally, would create a substantive compliance requirement, such language cannot be given effect absent proper notice and comment. Moreover, while the Department’s policy manual might be entitled to deference if the agency were interpreting a statute it was charged with enforcing or administering, the Department is not charged with enforcing or administering the Georgia Pharmacy Practice Act. *See id.* § 26-4-20(b) (“The responsibility for enforcement of the provisions of this chapter shall be vested in the Georgia State Board of Pharmacy.”); *see also Pruitt Corp. v. Ga. Dep’t of Cmty. Health*, 284 Ga. 158, 159-60 (2008) (acknowledging that “judicial deference is to be afforded the agency’s interpretation of statutes it is charged with enforcing or administering,” but expressly declining to decide whether all manualized policies of the Department are entitled to deference); *accord Cook v. Glover*, 295 Ga. 495, 501 (2014). Thus, the Department’s Manual is not entitled to deference on this issue and cannot be used to support the Department’s denial of payment.

practitioner's handwritten, visual image, or electronic signature. *See* Ga. Comp. R. & Regs. 480-10-15, 480-27-.02(1), and 480-27-.04(5)(b). Georgia law requires that the pharmacy maintain the original prescription record for at least two years (the "Original Prescription Requirement"). Ga. Comp. R. & Regs. 480-27-.05(a); *but see* Pharmacy Services Manual § 603 (requiring pharmacies to maintain prescription documentation for five years to support claims submitted for Medicaid reimbursement).

In addition to the document retention requirement applicable to original prescriptions, the Original Prescription Requirement requires that "[a]ny refill information subsequently authorized by a practitioner must be maintained in the manner required by [the Georgia Pharmacy Practice Act § 26-4-80(e)]." Ga. Comp. R. & Regs. 480-27-.05(a). In turn, Georgia Pharmacy Practice Act § 26-4-80(e) (referred to herein as the "Refill Rule") instructs pharmacists to record subsequent refill authorizations on the back of the original prescription "or on some other uniformly maintained record." *Id.* The full text of the Refill Rule provides:

Except as authorized under subsection (j) of this Code section, a prescription may not be refilled without authorization. When refills are dispensed pursuant to authorization contained on the original prescription or when no refills are authorized on the original prescription but refills are subsequently authorized by the practitioner, the refill authorization shall be recorded on the original prescription document and the record of any refill made shall be maintained on the back of the original prescription document or on some other uniformly maintained record and the dispensing pharmacist shall record the date of the refill, the quantity of the drug dispensed, and the dispensing pharmacist's initials; provided, however, that an original prescription for a Schedule III, IV, or V controlled substance which contains no refill information may not be authorized to be refilled more than five times or after six months from the date of issuance, whichever occurs first. Authorization for any additional refill of a Schedule III, IV, or V controlled substance prescription in excess of five refills or after six months from the date of issuance of the prescription shall be treated as a new prescription.

O.C.G.A. § 26-4-80(e).

The Refill Rule therefore contemplates that, although refills may later be authorized, the prior, initial prescriber authorization event remains the “original prescription.” *See id.* (noting that a dispensing pharmacist may record refill authorizations “on the original prescription”); *accord* Ga. Comp. R. & Regs. 480-27-.05(c)(9) (distinguishing a “refill order” from a “new prescription,” providing that when prescription information is maintained in an automated electronic data processing system, such information must include, among other things, an “[i]ndication whether drugs are being dispensed pursuant to *a new prescription or for a refill order*”) (emphasis added).

Indeed, the Refill Rule sets forth very specific and limited circumstances under which certain refill authorizations for Schedule III, IV, and V controlled substances may constitute “a new prescription.” In all other circumstances — including all of the Claims in this case, which are for legend drugs, not controlled substances — a subsequent refill authorization does not constitute a new prescription for purposes of the Original Prescription Requirement.

Further, the Refill Rule by its terms permits recordkeeping in any “uniformly maintained record,” and expressly does not require that records memorializing refill events be maintained in hard copy (e.g., on the back of the original prescription document). *See id.*; *see also id.* § 26-4-80(i) (providing that an oral authorization from a prescriber’s agent for a prescription drug refill “must be recorded on the original prescription drug order or other record”) (emphasis added). Any such requirement for hard copy recordkeeping would be incompatible with modern, electronic prescription fulfillment technology in use across the pharmaceutical industry and would be incongruous with widespread industry practice.

Georgia law does not prohibit pharmacies from storing original prescriptions, refill documentation, or other notations and records relevant to prescription drug orders in an electronic

database. To the contrary, Pharmacy Board Rules expressly *permit* recordkeeping in an automated electronic data processing system. *See generally* Ga. Comp. R. & Regs. 480-27-.01 to -.10.

Finally, Georgia law does not prohibit pharmacies from assigning a new prescription number to a subsequent refill authorization in order to facilitate accurate and efficient prescription tracking and recordkeeping. While pharmacies are required to assign prescription numbers, there is no Georgia statute or regulation that prohibits a given prescription from being assigned and tracked under more than one prescription number over the course of its lifetime. As an example, when an existing prescription is transferred from one dispensing pharmacy to another, a new prescription number is assigned by the receiving pharmacy (which would not be expected to have the same prescription numbering system as the sending pharmacy), even though no new prescription has been authorized. In sum, Georgia law requires only that a prescription be assigned a unique prescription number; not that a given prescription must maintain the *same* unique prescription number for every refill over its lifetime. *See* Ga. Comp. R. & Regs. 480-10-.15(8), 480-27-.03(c), 480-27-.05(a), and 480-27-.05(c)(2).

C. Burden of Proof

The Department bears the burden to show that each of the Claims are not reimbursable because they do not comply with Georgia law. Ga. Comp. R. & Regs. 616-1-2-.07. The standard of proof is a preponderance of the evidence. Ga. Comp. R. & Regs. 616-1-2-.21(4). Accordingly, the Department must prove by a preponderance of the evidence that the Claims fail to comply with the Original Prescription Requirement. The Department has failed to do so.

D. Copy/Created Records Documenting Changes that Do Not Require Subsequent Prescriber Authorization Are Annotations of Existing Prescriptions that Comply with the Original Prescription Requirement.

Documentation for 73 of the 91 Claims is found behind Tab B of Petitioner's Exhibit 1. These records include both an original prescription record and at least one related prescription drug

dispensation record that was created using the Copy/Create functionality. These Copy/Created records were generated for a variety of reasons, but all arise from Non-Authorization Events, and as such, none of the Copy/Created records required or involved prescriber authorization. Indeed, many of the events that initiated the Copy/Created record did not change the prescription at all. These 73 records found behind Tab B of Petitioner's Exhibit 1 will be referred to as Non-Authorization Records.

As an initial matter, the Department presented no evidence regarding the vast majority of these Non-Authorization Records, and what sparse testimony was offered was rebutted by the Petitioner's witnesses. Thus, the Department has failed to carry its burden to show that these Non-Authorization Records fail to satisfy the Original Prescription Requirement, or any provision of Georgia law.

Similarly, the Department's written submissions fail to articulate any basis upon which Non-Authorization Records fail to satisfy Georgia law. The Department has yet to identify where the record keeping methodology utilized by Walgreens does not satisfy the record keeping requirements.

Moreover, the Non-Authorization Records satisfy the Original Prescription Requirement. Walgreens maintains the original prescription records for each of these Non-Authorization Records, which are recorded and maintained within the Intercom Plus system based on how they were transmitted to the pharmacy. Whether in hard copy, faxed, telephonically transmitted, or electronically transmitted, the Non-Authorization Records include an original prescription (i.e., the first-in-time valid prescription drug order pursuant to which a prescriber authorized the initial dispensation of each drug) in the form transmitted to Walgreens by the prescriber. These original prescriptions include all seven required elements of a valid prescription drug order (*see* Ga. Comp.

R. & Regs. 480-10-.15, 480-27-.02(1), and 480-27-.04(5)(b)) and satisfy the Original Prescription Requirement.

Each of the Non-Authorization Records behind Tab B also includes at least one record documented using Copy/Create. Georgia law provides that every prescription drug order shall include documentation of the prescriber's authorization. *See* O.C.G.A. § 26-4-80(i); Ga. Comp. R. & Regs. 480-10-.15, 480-27-.02(1) and (2), and 480-27-.04(5)(b). The Copy/Created records associated with Non-Authorization Records memorialize events in the life of a prescription drug order that do not require or involve subsequent prescriber authorization. They cannot constitute “new” original prescriptions subject to the Original Prescription Requirement because they do not involve the authorization of a new prescription.

It is undisputed that state-licensed pharmacists' scope of practice affords them discretion to make notes and record certain events during the life of an existing prescription drug order, and to document such Non-Authorization Events — e.g., prescription transfers, NDC updates, and store and fill later events — in updated dispensing records associated with a patient's existing prescription. No Georgia law prohibits the creation of these records or requires them to be kept in any particular form. While Georgia regulations govern recordkeeping requirements when pharmacies utilize electronic recordkeeping systems (*see* Pharmacy Board Rules, Chapter 480-27), no rules restrict the specific technological mechanisms or database functionalities that may be used to record information in an electronic system. *See* Ga. Comp. R. & Regs. 480-27-.03, (“Records of Dispensing”) and 480-27-.05 (“Record-Keeping When Utilizing an Automated Data Processing System”). Indeed, such granular and prescriptive electronic documentation requirements would be impractical in the ever-evolving landscape of electronic prescription documentation systems and capabilities.

Even assigning a new prescription number to such records does not establish that a new prescription drug order has been created. Georgia law is clear that prescription numbers must be assigned for recordkeeping purposes. *See* Ga. Comp. R. & Regs. 480-10-.15(8) (requiring “[a] serial number assigned by the Pharmacist so that Prescription Drug Orders may be filed in a numerical and retrievable sequence”). Importantly, however, the identity of the original prescription that applies to any given drug dispensation is determined by the scope and nature of the prescriber’s authorization — i.e., the specific medication and quantity authorized to be dispensed, and to whom. Whether the prescriber has, in fact, authorized the dispensation clearly does not depend upon the pharmacist’s assignment of a prescription number. A prescription number, while essential for recordkeeping purposes, does not itself result in a new prescription, nor does it modify the scope of the prescriber’s authorization for an existing prescription.

In sum, the documentation furnished by Walgreens in connection with these Non-Authorization Records evidences the original prescriptions underlying each of the Copy/Created records associated with these 73 Claims complies with the Original Prescription Requirement.

E. Copy/Created Records Documenting Updates that Do Require Subsequent Prescriber Authorization Modify Existing Prescriptions that Comply with the Original Prescription Requirement

Documentation for 18 of the 91 Claims is found behind Tab A of Petitioner’s Exhibit 1. Each of the records includes both an original prescription record, and at least one related dispensation record that was created using the Copy/Create functionality to document an Authorization Event. Specifically, these Copy/Created records were generated to document prescriber authorization of subsequent refills of an existing prescription. These 18 records found behind Tab A of Petitioner’s Exhibit 1 will be referred to as Authorization Records.

First and foremost, it must be stressed (as is also the case for the Non-Authorization Records discussed above), the Department presented no evidence regarding the vast majority of

these Authorization Records. What sparse testimony was offered was rebutted by the Walgreens' witnesses. The Department has thus failed to carry its burden to show that these Authorization Records fail to satisfy the Original Prescription Requirement, or any provision of Georgia law. Again, the Department's failure to identify its objections as to these claims requires that Walgreens' appeal must be sustained.

But even moving past the Department's failure on the burden of proof issue, the Court is persuaded that the Authorization Records satisfy the Original Prescription Requirement.

Under the Refill Rule, pharmacists are *not* required to obtain and record a brand-new original prescription for subsequent refill authorizations. Rather, pharmacists are directed to record additional authorized refills on the existing prescription or in another "uniformly maintained record." O.C.G.A. § 26-4-80(e). The Refill Rule itself recognizes that a prescriber's subsequent refill authorization is not itself a new "original prescription." For this reason, the Copy/Created records at issue for each of these 18 claims for Authorization Events are properly regarded as supplemental documentation of additional refills that relate back to, and are premised upon, an underlying original prescription.¹²

¹² At the hearing, the Department's witness testified that that any refill authorization would create a new prescription. *See* Hr'g Recording at 00:49:16 – 00:50:33 (M. Reed test.); 02:14:15 – 02:14:51, 02:48:06 – 02:48:16 (P. D'Alba test.). That interpretation would read the Refill Rule out of existence entirely and must be rejected. The Department also argued in its written submissions that the Refill Rule does not apply to subsequently authorized refills if the original prescription initially authorized some refills, and only applies when zero refills were initially authorized. To the extent the Department maintains that position, it is without merit. The interpretation tortures the language of the Refill Rule and is inconsistent with pharmacy practice. *See* Hr'g Recording at 04:18:59 – 04:19:38 (M. Oppong test.). The better reading of the Refill Rule simply distinguishes between refills "dispensed pursuant to authorization contained on the original prescription" versus those refills dispensed pursuant to a subsequent authorization — i.e., because when the refill was dispensed, the original prescription no longer authorized any more refills (regardless of whether the original prescription authorized some number of refills when first written). This interpretation is consistent with Pharmacy Board Rules interpreting the Refill Rule, which contemplate that additional refills may be authorized for original prescriptions that initially included some authorized refills that have been fully dispensed. *See, e.g.,* Ga. Comp. R. & Regs. 480-22-.08(4)(c) (permitting a prescribing practitioner to authorize "additional refills" of an "original prescription drug order" for a controlled substance, provided that "[t]he quantity of each additional refill authorized is equal to or less than the quantity authorized for the initial filling of the original prescription drug order," among other requirements).

For Authorization Records, Walgreens maintains the original prescription record that includes all seven required elements of a valid prescription drug order (*see, e.g.*, Ga. Comp. R. & Regs. 480-10-.15, 480-27-.02(1), and 480-27-.04(5)(b)) and one or more supplemental Copy/Created records documenting subsequent events in the life of the prescription, including the Copy/Created record at issue that documents the prescriber's authorization of one or more additional refills of the existing prescription. The vast majority of the refill authorization records at issue here document oral prescriber authorization that has been reduced to writing by the pharmacist (or pharmacy technician), consistent with Georgia rules governing telephonic prescription drug orders (*see* Ga. Comp. R. & Regs. 480-27-.01(s) and 480-10-.09) and with the Original Prescription Requirement (*see id.* at 480-27-.05(a)). Rather than memorializing the refill event in a hard copy record, Walgreens pharmacists use Copy/Create to document the subsequent refill authorization in a new database record that is linked to the original prescription, consistent with the Refill Rule. *See* O.C.G.A. § 26-4-80(e) (permitting refill authorization to be recorded on the back of the original prescription or on some other "uniformly maintained record").

The Department has failed to point to any requirement in the Georgia Pharmacy Practice Act or the Pharmacy Board Rules that the pharmacist's transcription of the prescriber's oral authorization be handwritten. Such a reading would be inconsistent with the vast body of Georgia law and precedent that interpret "writing" as including words, letters, and numbers that have been documented electronically.

For the reasons discussed above, the fact that the Copy/Created record is assigned a new prescription number within the Copy/Create software system for identification does not mean that a new prescription drug order has been generated. Rather, consistent with the Refill Rule, a valid prescription drug order may be supplemented and extended if the prescriber subsequently

authorizes additional refills on the existing prescription. The pharmacist's assignment of a new prescription number for convenience and tracking purposes is immaterial.

The documentation furnished by Walgreens in connection with these Authorization Records evidences the original prescriptions underlying each of the Copy/Created refill authorization records associated with the 18 such Claims in this appeal, and as such, complies with the Original Prescription Requirement.

F. Copy/Created Records that Record a Subsequent Prescriber Authorization Event Independently Satisfy the Original Prescription Requirement, Though They Are Not Required to Do So

Even if Copy/Created records that memorialize subsequent Authorization Events constitute new original prescriptions, those records independently satisfy the Original Prescription Requirement. Copy/Created records memorializing Authorization Events include documentation of all seven elements of a valid prescription drug order. *See, e.g.*, Ga. Comp. R. & Regs. 480-10-.15, 480-27-.02(1), and 480-27-.04(5)(b). As established at the hearing, documentation evidencing subsequent prescriber authorization depends on the manner of authorization. For subsequent Authorization Events authorized verbally, Copy/Created records contain an annotation documenting the prescriber's authorization, as verbally provided to the pharmacist or pharmacy technician, in compliance with the Original Prescription Requirement and applicable Georgia laws and rules governing oral prescription drug orders. *See* O.C.G.A. §§ 26-4-80(e), (i); Ga. Comp. R. & Regs. 480-27-.01(s), 480-10-.09, and 480-27-.05(a).

Georgia law does not prohibit Walgreens from recording the elements of an original prescription in an electronic format, and certainly does not restrict the technological mechanism used to update validly maintained electronic records. Indeed, Copy/Create is simply the name of a database functionality that facilitates documentation, organizes information, and ensures accuracy, continuity, and reliable accessibility of patient records. Where, as here, all elements of

a valid prescription drug order are present — including documentation of prescriber authorization — there is nothing *per se* improper about using an electronic database to house prescription records or updating an electronic database using the Copy/Create functionality.

V. SUMMARY AND CONCLUSION

The Court has struggled and continues to struggle to understand the Department's Objections to the Claims in this case. Walgreens' Copy/Create functionality is consistent with the prevailing standard of practice throughout the pharmacy industry and is perfectly capable of satisfying Georgia laws and regulations governing prescription drug order documentation requirements, including the Original Prescription Requirement, the Refill Rule, oral prescription documentation rules, and other relevant provisions of Georgia law.

Throughout this case, the Department has repeatedly asserted and continues to assert that the "original prescription" in these claims is not maintained as required and this is the basis for a blanket disallowance. But beyond these continuous and generalized assertions, the Department has failed to introduce intelligible evidence as to why the documentation maintained by Petitioner using the Copy/Create electronic record system and the documentation for the Claims in this case as reviewed by this Court is not adequate to satisfy these criteria and does not comply with these requirements. To the contrary, the evidence adduced at the hearing shows that all the required information regarding the Claims is readily available and accessible through terminals on site in "sight-readable" form. The Court can confirm from reviewing the printed-out documentation submitted that the documentation is indeed "sight-readable". There is no testimony to the contrary.

The best the Court can surmise from the testimony of the Department's witnesses at the hearing and the filings of the Department is that the alleged failures to which the Department objects are: (i) the assignment of a new document number to subsequent pages in a prescription file when a document is replicated or when supplemented using the Intercom Plus and Copy/Create

software programs; and (ii) the documentation of notes through typing them directly into the Copy/Create Software in an electronic file as an electronic document instead of these being handwritten and then scanned into the computer records. But the Department has failed to show why this is impermissible under governing law.

VI. ORDER

For the reasons set forth above, the Department's findings regarding the Claims and seeking recoupment in this matter are **REVERSED**.

SO ORDERED this 6th day of June, 2022.



Charles R. Beaudrot
Administrative Law Judge