

IN THE SUPREME COURT OF TENNESSEE
AT NASHVILLE
May 30, 2019 Session

<p>FILED 04/29/2020 Clerk of the Appellate Courts</p>
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MELISSA MARTIN, ET AL. v. ROLLING HILLS HOSPITAL, LLC, ET AL.

**Appeal by Permission from the Court of Appeals
Circuit Court for Williamson County
No. 2016-8 Michael Binkley, Judge**

No. M2016-02214-SC-R11-CV

We granted permission to appeal to clarify the role of prejudice in a court’s determination of whether a plaintiff in a health care liability action substantially complied with the statutory pre-suit notice requirements of Tennessee Code Annotated section 29-26-121 (Supp. 2019) (“Section 121”) and to clarify the burdens each party bears when seeking to establish, or to challenge, compliance with Section 121. We hold that prejudice is relevant to the determination of whether a plaintiff substantially complied with Section 121, but it is not a separate and independent analytical element. We also hold that a plaintiff bears the initial burden of either attaching documents to her health care liability complaint demonstrating compliance with Section 121 or of alleging facts in the complaint demonstrating extraordinary cause sufficient to excuse any noncompliance with Section 121. A defendant seeking to challenge a plaintiff’s compliance with Section 121 must file a Tennessee Rule of Civil Procedure 12.02(6) motion to dismiss for failure to state a claim. See Myers v. AMISUB (SFH), Inc., 382 S.W.3d 300, 307 (Tenn. 2012). A defendant’s Rule 12.02(6) motion must include allegations that identify the plaintiff’s noncompliance and explain “the extent and significance of the plaintiff’s errors and omissions and whether the defendant was prejudiced by the plaintiff’s noncompliance.” Stevens ex rel. Stevens v. Hickman Cmty. Health Care Servs., Inc., 418 S.W.3d 547, 556 (Tenn. 2013). One means of satisfying this burden is to allege that a plaintiff’s Section 121(a)(2)(E) medical authorization lacks one or more of the six core elements federal law requires for compliance with the Health Insurance Portability and Accountability Act of 1996 (“HIPAA”). See Pub. L. No. 104-191, 110 Stat. 1936 (1996) (codified as amended in scattered sections of 18, 26, 29, and 42 of the United States Code). Once a defendant files a Rule 12.02 motion that satisfies this prima facie showing, the burden then shifts to the plaintiff either to establish substantial compliance with Section 121—which includes the burden of demonstrating that the noncompliance did not prejudice the defense—or to demonstrate extraordinary cause that excuses any noncompliance. In this case, the defendants met their burden by showing that the plaintiffs’ medical authorizations lacked three of the six core elements federal law requires for HIPAA compliance. This showing shifted the burden to the plaintiffs, and they failed to establish either substantial

compliance or extraordinary cause to excuse their noncompliance. As a result of this noncompliance with Section 121(a)(2)(E), the plaintiffs were not entitled to the 120-day extension of the statute of limitations. Therefore, their first lawsuit, filed after the one-year statute of limitations expired, was not “commenced within the time limited by a rule or statute of limitation,” Tenn. Code Ann. § 28-1-105(a) (2017), so the plaintiffs cannot rely on the one-year savings statute to establish the timeliness of this lawsuit. Accordingly, we reverse the judgment of the Court of Appeals and reinstate the trial court’s judgment dismissing the plaintiffs’ health care liability action as time-barred.

**Tenn. R. App. P. 11 Appeal by Permission; Judgment of the Court of Appeals
Vacated; Judgment of the Circuit Court Reinstated**

CORNELIA A. CLARK, J., delivered the opinion of the Court, in which JEFFREY S. BIVINS, C.J., and SHARON G. LEE, and ROGER A. PAGE, JJ., joined. HOLLY KIRBY, J., filed an opinion concurring in part and dissenting in part.

Edward A. Hadley, Linda A. Nathanson, and Matthew J. Buchbinder, Nashville, Tennessee, for the appellant, Matthew Karl, M.D.

Ashley D. Cleek and Brandon J. Stout, Jackson, Tennessee, for the appellants, Rolling Hills Hospital, LLC, and Universal Health Services, Inc.

Trudy Bloodworth, Nashville, Tennessee; and Dawn M. Smith, Dallas, Texas (pro hac vice), for the appellees, Melissa Martin, on behalf of herself and minor children C.H., A.H., Jr., wrongful death beneficiaries of Chelsey Elizabeth Kay Helwig, deceased, and James Harrison.

W. Bryan Smith, Memphis, Tennessee; John Vail, Washington, D.C.; and Brian G. Brooks, Greenbriar, Arkansas, for Amicus Curiae Tennessee Trial Lawyers Association.

Christopher A. Vrettos, Nashville, Tennessee, for Amicus Curiae Tennessee Defense Lawyers Association.

OPINION

I. Factual and Procedural Background¹

On June 25, 2013, twenty-three-year-old Chelsey Elizabeth Kay Helwig (“Ms. Helwig” or “decedent”) presented to Skyline Medical Center complaining of suicidal ideation and depressive disorder. After an examination, she was transferred to Rolling Hills Hospital, LLC (“Rolling Hills”), a mental health facility. On June 26, 2013, she was admitted to Rolling Hills for specialized in-patient psychiatric care for suicidal ideation and detoxification from opiates, benzodiazepines, alcohol, and cocaine. Dr. Matthew Karl (“Dr. Karl”), who specialized in psychiatric medicine and provided care and treatment to patients at Rolling Hills, evaluated Ms. Helwig and prescribed medications for her. On the morning of June 28, 2013, Rolling Hills’ staff discovered Ms. Helwig unresponsive in her hospital room. They began CPR and called 9-1-1. Emergency personnel arrived a short time later and transferred her to Williamson Medical Center. Subsequently, Ms. Helwig was transferred to Vanderbilt Medical Center, where she died later that day.

On October 17, 2014, the decedent’s mother, Melissa Martin, and her father, James Harrison, filed a health care liability action. They sued in their individual capacities, and the decedent’s mother also sued on behalf of the decedent’s estate and the decedent’s two minor children (collectively “the Plaintiffs”). The Plaintiffs named as defendants Rolling Hills, Dr. Karl, and Universal Health Services, Inc. (“UHS”), the parent company that owned, managed, controlled, and/or operated Rolling Hills (collectively “the Defendants”). The Plaintiffs alleged that the Defendants were negligent in their evaluation, treatment, monitoring, and care of the decedent and that their negligence caused her death.

As with any health care liability lawsuit, the Plaintiffs were required to provide the Defendants with written pre-suit notice at least sixty days before filing their health care liability action. See Tenn. Code Ann. § 29-26-121(a)(1). On October 4, 2013, approximately a year before they filed their complaint, the Plaintiffs attempted to comply with Section 121 by sending a letter to both Rolling Hills and UHS (collectively, “the Hospital Defendants”) notifying them of their intent to file suit. Along with each letter, the Plaintiffs included a separate document purporting to list “all providers being sent a

¹ Because this matter was dismissed on defense motions, this factual summary is taken from the complaint and other pleadings in the record on appeal. Citations and quotations in this opinion are to the current version of statutes because the relevant statutory text remains the same as it was when this matter began in the trial court.

notice[,]” but this document listed only Rolling Hills. The Plaintiffs also included two medical authorizations with each letter, but the Plaintiffs failed to list on any of these four authorizations the name and address of the provider authorized to release medical records. They also left blank the space on the medical authorizations designated for an expiration or event date. Finally, while the decedent’s mother signed the medical authorizations in her representative capacity, she failed to provide a description or documentation of her authority to act for the decedent.

The Plaintiffs first attempted to provide Dr. Karl with pre-suit notice several months later, on June 20, 2014. As with the Hospital Defendants, the Plaintiffs sent Dr. Karl a letter notifying him of their intent to file suit and included a separate document purporting to list “all providers being sent a notice[,]” but this document listed only Dr. Karl and Rolling Hills. Dr. Karl’s letter included two medical authorizations, but, like the medical authorizations sent to the Hospital Defendants, the Plaintiffs failed to list the name and address of the provider authorized to release medical records to Dr. Karl. The Plaintiffs also left blank the space on the medical authorizations designated for an expiration or event date. Finally, while the decedent’s mother signed the medical authorizations in her representative capacity, she failed to provide a description or documentation of her authority to act for the decedent.

As already noted, the document the Plaintiffs included with their October 2013 pre-suit notice letters to the Hospital Defendants did not list Dr. Karl as a provider who would be named as a defendant. Additionally, prior to filing the lawsuit, the Plaintiffs never informed the Hospital Defendants that they had sent Dr. Karl a pre-suit notice letter. Nor did the Plaintiffs ever send the Hospital Defendants a medical authorization permitting them to obtain the decedent’s medical records from Dr. Karl.

After the Plaintiffs filed their lawsuit in October 2014, the Defendants objected that the Plaintiffs had failed to provide pre-suit notice in compliance with Section 121.² However, before the trial court ruled on the matter, the Plaintiffs voluntarily nonsuited their lawsuit. Tenn. R. Civ. P. 41.01.³ On January 27, 2015, the trial court entered an order dismissing the lawsuit without prejudice.

² The record in this appeal does not indicate the manner in which the Defendants objected to the Plaintiffs’ pre-suit notice, but it is undisputed that the Defendants raised the issue before the Plaintiffs voluntarily nonsuited the action.

³ Rule 41.01 states in pertinent part:

(1) Subject to the provisions of Rule 23.05, Rule 23.06, or Rule 66 or of any statute, and except when a motion for summary judgment made by an adverse party is pending, the plaintiff shall have the right to take a voluntary nonsuit to dismiss an action

Less than a year later, on January 7, 2016, the Plaintiffs filed a second lawsuit alleging the same health care liability claims against the Defendants. To establish the timeliness of this second lawsuit, the Plaintiffs relied on the savings statute, which provides:

If the [original] action is commenced within the time limited by a rule or statute of limitation, but the judgment or decree is rendered against the plaintiff upon any ground not concluding the plaintiff's right of action, or where the judgment or decree is rendered in favor of the plaintiff, and is arrested, or reversed on appeal, the plaintiff, or the plaintiff's representatives and privies, as the case may be, may, from time to time, commence a new action within one (1) year after the reversal or arrest.

Tenn. Code Ann. § 28-1-105(a).

On January 28, 2016, the Hospital Defendants filed a joint motion to dismiss the second lawsuit as time-barred. The Hospital Defendants acknowledged that the Plaintiffs filed the first lawsuit within 120 days of the expiration of the statute of limitations and that the first lawsuit would have been timely had the Plaintiffs provided pre-suit notice substantially compliant with Section 121. See Tenn. Code Ann. § 29-26-121(c) (“When notice is given to a provider as provided in this section, the applicable statutes of limitations and repose shall be extended for a period of one hundred twenty (120) days”). The Hospital Defendants contended, however, that the Plaintiffs’ pre-suit notice was not substantially compliant with Section 121.⁴ In particular, the Hospital Defendants asserted that: (1) the Plaintiffs failed to mail the pre-suit notice letter to the Hospital Defendants’ registered agents for service of process, as required by Section 121(a)(3)(B)(ii); (2) the Plaintiffs’ medical authorizations lacked three core elements mandated by federal law and were therefore not HIPAA compliant as required by Section 121(a)(2)(E); and (3) the Plaintiffs failed to notify the Hospital Defendants that Dr. Karl

without prejudice by filing a written notice of dismissal at any time before the trial of a cause and serving a copy of the notice upon all parties

. . . .

(3) A voluntary nonsuit to dismiss an action without prejudice must be followed by an order of voluntary dismissal signed by the court and entered by the clerk. The date of entry of the order will govern the running of pertinent time periods.

⁴ It is undisputed that the Plaintiffs provided timely and fully compliant pre-suit notice to the Defendants before filing their second lawsuit. This appeal pertains only to the pre-suit notice the Plaintiffs provided before filing their first lawsuit.

was a potential defendant as required by Section 121(a)(2)(D). Because the Plaintiffs' pre-suit notice was not substantially compliant with Section 121, the Hospital Defendants asserted that the Plaintiffs were not entitled to the 120-day extension of the statute of limitations, so their first lawsuit was not timely filed. As a result, the Hospital Defendants asserted that the Plaintiffs could not rely on the one-year savings statute to establish the timeliness of their second lawsuit.

In March 2016, Dr. Karl filed his own motion to dismiss in which he joined the Hospital Defendants' motion to dismiss and adopted their arguments.⁵ In addition, Dr. Karl asserted that he had attempted to use the medical authorization the Plaintiffs provided "to obtain [Rolling Hills'] records pertaining to the decedent[.]" but "[t]he hospital [had] declined to produce the records because of the defective authorization." Dr. Karl argued that the Plaintiffs' noncompliance thus deprived him of "the opportunity to evaluate the medical records and the merits of the [Plaintiffs'] claim prior to suit being filed."

In separate responses to the motions to dismiss, the Plaintiffs argued that they had substantially complied with the pre-suit notice requirements of Section 121 and that any noncompliance had not prejudiced the Defendants. The Plaintiffs did not rely upon or attempt to establish that extraordinary cause excused their noncompliance. As to prejudice, the Plaintiffs did not submit affidavits but merely argued in their responses to the motions that they had engaged in settlement negotiations with the Hospital Defendants from April to June 2014, and that these negotiations "equipped [the Hospital Defendants] with the means to evaluate the substantive merits of [the Plaintiffs'] claims by early discovery and early access to [the decedent's] medical records." The Plaintiffs stated that the Hospital Defendants called Dr. Karl's conduct into question during the settlement negotiations, so the Hospital Defendants clearly were aware that Dr. Karl was a potential defendant. The Plaintiffs also argued without relying upon any affidavit or defense admission that the Hospital Defendants were not prejudiced by any deficiencies in the pre-suit notice relating to Dr. Karl because he was an employee or agent of Rolling Hills and had no relevant medical records aside from those the Hospital Defendants already had in their possession.

On August 4, 2016, the trial court held a hearing on the Defendants' motions to dismiss. By a written order entered on September 19, 2016, the trial court granted the Defendants' motions and dismissed the lawsuit. The trial court based its decision solely

⁵ For reasons that are not apparent, the record contains two identical motions to dismiss by Dr. Karl, one filed on March 4 and another filed on March 16, 2016.

on the Plaintiffs' failure to provide the Defendants with HIPAA-compliant medical authorizations as required by Section 121(a)(2)(E).⁶ The trial court pointed out that the medical authorizations "failed to indicate the providers that were authorized to make required disclosures, failed to list an expiration date, and left blank section B on the [] authorization form." When rejecting the Plaintiffs' argument that the Defendants were not prejudiced by the defective authorizations, the trial court quoted an earlier decision of the Court of Appeals stating, "defendants were prejudiced by the fact that they were unable to obtain the patient's medical records due to some flaw in the medical authorization." Hughes v. Henry Cnty. Med. Ctr., No. W2014-01973-COA-R3-CV, 2015 WL 3562733, at *4 (Tenn. Ct. App. June 9, 2015). The trial court also rejected the Plaintiffs' argument that the Defendants were not prejudiced "because they already had possession of the relevant documents." The trial court explained that the "omissions" on the medical authorizations "were significant because without this information, even if [the] Defendants were already in possession of certain documentations, the authorizations were useless" and "would not have allowed Defendants to request or obtain records from any of the other providers." The trial court also pointed out that the Plaintiffs had failed to respond with any showing of extraordinary cause to excuse the noncompliance. See Tenn. Code Ann. § 29-26-121(b) ("The court has discretion to excuse compliance with this section only for extraordinary cause shown."). Based on these findings, the trial court ruled: "Due to their substantial non-compliance [with Section 121(a)(2)(E)], Plaintiffs were not originally entitled to the 120-day extension of the statute of limitations under . . . Section 29-26-121(c). Without the 120-day extension, Plaintiffs' initial filing was time-barred, and as such, the current matter must be dismissed." The Plaintiffs appealed.

The Court of Appeals reversed. Martin v. Rolling Hills Hosp., LLC, No. M2016-02214-COA-R3-CV, 2018 WL 3097231, at *9 (Tenn. Ct. App. June 22, 2018), perm. app. granted (Tenn. Nov. 16, 2018). The intermediate appellate court commented that the trial court "[had] not explain[ed] its conclusion that the authorizations were 'useless' or reach[ed] the question of whether Defendants were prejudiced by Plaintiffs' errors." Id. at *8. Addressing Dr. Karl's "attempt[] to use the authorizations to obtain records," id. at

⁶ The trial court also determined that the Defendants were not prejudiced by the Plaintiffs' failure to include in their pre-suit notice the names and addresses of all providers sent pre-suit notice, as required by Section 121(a)(2)(D) or by the Plaintiffs' failure to mail pre-suit notice letters to Defendants' registered agents for service of process as required by Section 121(a)(3)(B)(ii). We need not address these determinations because our holding that the Plaintiffs failed to substantially comply with Section 121(a)(2)(E) is dispositive.

*8, the Court of Appeals observed that the letters exchanged between counsel for Dr. Karl and Rolling Hills did not “reflect a good faith attempt on the part of Defendants to secure the records,” but instead showed “an effort by their counsel to establish a record upon which to present this argument[,]” id. at *8 n.7. The Court of Appeals determined that the Defendants had not shown prejudice because Dr. Karl was an “employee and/or ostensible agent” of Rolling Hills, and UHS was “merely a corporate entity (not Provider/Health Plan) and obviously had no treatment records regarding Ms. Helwig.” Id. at *9. Based on its conclusions that the Plaintiffs had substantially complied with Section 121(a)(2) and that the Defendants had failed to show prejudice from the Plaintiffs’ noncompliance, the Court of Appeals concluded that the Plaintiffs’ first lawsuit was timely filed and that the savings statute applied to their second lawsuit. Id. Accordingly, the Court of Appeals reversed the trial court’s decision and remanded the case for further proceedings. Id.

This Court granted the Defendants’ applications for permission to appeal and directed the parties to address:

- 1) the proper role of prejudice in the substantial compliance analysis and determination; and
- 2) the proper burden of production and/or proof with respect to the presence or absence of prejudice for purposes of the substantial compliance analysis and determination, including whether or not the Court should consider the adoption of a rebuttable presumption of prejudice where the pre-suit notice is not accompanied by a medical authorization which is facially compliant with HIPAA.

Martin v. Rolling Hills Hospital, No. M2016-02214-SC-R11-CV (Tenn. Nov. 16, 2018) (Order) (granting applications for permission to appeal).

II. Standard of Review

The Defendants filed motions to dismiss under Rule 12.02(6) of the Tennessee Rules of Civil Procedure, arguing that the lawsuit is time-barred by the one-year statute of limitations because the savings statute does not apply. A Rule 12.02(6) motion is an appropriate means of invoking the statute of limitations as a ground for dismissing a complaint. Redwing v. Catholic Bishop for Diocese of Memphis, 363 S.W.3d 436, 455 n.11 (Tenn. 2012). The Defendants’ statute of limitations argument is also premised on the assertion that the Plaintiffs’ first lawsuit was not timely filed because the Plaintiffs failed to provide pre-suit notice substantially compliant with Section 121. Rule 12.02(6) is the proper vehicle for challenging a plaintiff’s compliance with the pre-suit notice requirements of Section 121. Myers, 382 S.W.3d at 307. However, because the

Defendants submitted matters outside the pleadings in support of their 12.02(6) motions, the motions “shall be treated as [motions] for summary judgment” Tenn. R. Civ. P. 12.02; see Runions v. Jackson-Madison Cnty. Gen. Hosp. Dist., 549 S.W.3d 77, 81 n.5 (Tenn. 2018). Summary judgment is appropriate when “the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law.” Tenn. R. Civ. P. 56.04. We review a trial court’s decision on a motion for summary judgment de novo without a presumption of correctness. Rye v. Women’s Care Ctr. of Memphis, M PLLC, 477 S.W.3d 235, 250 (Tenn. 2015) (citing Bain v. Wells, 936 S.W.2d 618, 622 (Tenn. 1997)).

“[W]hether [Plaintiffs] ha[ve] demonstrated extraordinary cause that would excuse compliance with [Section 121] is a mixed question of law and fact, and our review of that determination is de novo with a presumption of correctness applying only to the trial court’s findings of fact and not to the legal effect of those findings.” Myers, 382 S.W.3d at 307. Additionally, issues of statutory construction are questions of law, to which de novo review applies, with no presumption of correctness afforded to lower court decisions. Thurmond v. Mid-Cumberland Infectious Disease Consultants, PLC, 433 S.W.3d 512, 516-17 (Tenn. 2014) (citing Baker v. State, 417 S.W.3d 428, 433 (Tenn. 2013)). Thus, de novo review applies to the issues presented in this appeal.

III. Analysis

At least sixty days before filing a complaint alleging a health care liability claim, a plaintiff in Tennessee must give written notice of the claim to each health care provider that will be named as a defendant in the lawsuit. Tenn. Code Ann. § 29-26-121(a)(1) (“Any person, or that person’s authorized agent, asserting a potential claim for health care liability shall give written notice of the potential claim to each health care provider that will be a named defendant at least sixty (60) days before the filing of a complaint based upon health care liability in any court of this state.”). This statutory requirement of timely, written pre-suit notice is mandatory and may be satisfied only by strict compliance; substantial compliance is inadequate. Myers, 382 S.W.3d at 309; see also Runions, 549 S.W.3d at 86.

Section 121(a)(2) defines the information—the content—that a plaintiff must include in the pre-suit notice:

The notice shall include:

- (A) The full name and date of birth of the patient whose treatment is at issue;

- (B) The name and address of the claimant authorizing the notice and the relationship to the patient, if the notice is not sent by the patient;
- (C) The name and address of the attorney sending the notice, if applicable;
- (D) A list of the name[s] and address[es] of all providers being sent a notice; and
- (E) A HIPAA compliant medical authorization permitting the provider receiving the notice to obtain complete medical records from each other provider being sent a notice.

Tenn. Code Ann. § 29-26-121(a)(2); John A. Day, Med Mal Makeover 2009 Act Improves on '08: The New New Medical Malpractice Notice & Certificate of Good Faith Statutes, 45 Tenn. B.J. 14, 14-16 (July 2009) (discussing Section 121(a)(2) and the pre-suit notice content requirements). These statutory content requirements are directory and may be satisfied by substantial compliance. Stevens, 418 S.W.3d at 555 (evaluating whether a plaintiff substantially complied with Section 121(a)(2)(E)); see also Arden v. Kozawa, 466 S.W.3d 758, 762-64 (Tenn. 2015) (holding that the requirements of Section 121(a)(3)(B) and (a)(4) may be satisfied through substantial compliance); Thurmond, 433 S.W.3d at 520 (holding that the affidavit requirement of Section 121(a)(3)(B) and (a)(4) may be satisfied by substantial compliance).

This Court has explained the distinct but interdependent purposes Section 121 serves, stating that it “ensures that a plaintiff give[s] timely notice to a potential defendant of a health care liability claim so it can investigate the merits of the claim and pursue settlement negotiations before the start of the litigation.” Runions, 549 S.W.3d at 86 (citing Foster v. Chiles, 467 S.W.3d 911, 915 (Tenn. 2015)). “Pre-suit notice benefits the parties by promoting early resolution of claims, which also serves the interest of judicial economy.” Id. (citing Foster, 467 S.W.3d at 915). The first three content requirements of Section 121(a)(2) “facilitate early resolution of healthcare liability claims by requiring plaintiffs to advise defendants who the plaintiff is, how to reach him or her, and how to contact his or her attorney.” Stevens, 418 S.W.3d at 554. The last two requirements “serve an investigatory function, equipping defendants with the actual means to evaluate the substantive merits of a plaintiff’s claim by enabling early discovery of potential co-defendants and early access to a plaintiff’s medical records.” Id.

With these principles in mind, we return to the dispositive issue in this appeal: whether the Plaintiffs substantially complied with Section 121(a)(2) before filing their first lawsuit. Stevens ex rel. Stevens v. Hickman Community Health Care Services, Inc., provides the framework for our analysis of this issue. In Stevens, the plaintiff failed to provide a “HIPAA compliant medical authorization permitting the provider receiving the

notice to obtain complete medical records from each other provider being sent a notice.” Id. at 555 (quoting Tenn. Code Ann. § 29-26-121(a)(2)(E)). We pointed out that HIPAA generally “prohibits medical providers from using or disclosing a plaintiff’s medical records without a fully compliant authorization form.” Id. We therefore declared that “it is a threshold requirement of [Section 121] that the plaintiff’s medical authorization must be sufficient to enable defendants to obtain and review a plaintiff’s relevant medical records.” Id. And we emphasized that “[f]ederal regulations” mandate the following six “core” elements for a HIPAA compliant medical authorization:

- (i) A description of the information to be used or disclosed that identifies the information in a specific and meaningful fashion.
- (ii) The name or other specific identification of the person(s), or class of persons, authorized to make the requested use or disclosure.
- (iii) The name or other specific identification of the person(s), or class of persons, to whom the covered entity may make the requested use or disclosure.
- (iv) A description of each purpose of the requested use or disclosure
- (v) An expiration date or an expiration event that relates to the individual or the purpose of the use or disclosure
- (vi) Signature of the individual and date. If the authorization is signed by a personal representative of the individual, a description of such representative’s authority to act for the individual must also be provided.

Id. at 555-56 (quoting 45 C.F.R. § 164.508(c)(1) (2013)). We noted that omitting any of these core elements may render a medical authorization noncompliant with HIPAA and ineffective “to enable defendants to obtain and review a plaintiff’s relevant medical records.” Id. at 555 (citing 45 C.F.R. § 164.508(a)(1)). We also emphasized that “[t]he penalties imposed upon covered entities that wrongfully disclose or obtain private health information in violation of HIPAA are . . . extremely severe, with such entities facing punishment of up to \$50,000 per offense and/or imprisonment of up to one year for non-compliance.” Stevens, 418 S.W.3d at 555 n.6 (citing 42 U.S.C.A. § 1320d-6). We ruled that, when determining whether a plaintiff “has substantially complied with [Section 121(a)(2)(E),] a reviewing court should consider the extent and significance of the plaintiff’s errors and omissions and whether the defendant was prejudiced by the plaintiff’s noncompliance.” Id. at 556.

Applying that analysis, we noted that the plaintiff in Stevens had conceded that her medical authorization provided ““very little benefit”” to the defendants and failed to comply with HIPAA. Id. This Court agreed and pointed out that the plaintiff’s medical authorization failed to satisfy at least three of the six core elements mandated by federal law for HIPAA compliance. Id. In particular, the medical authorization:

lacked a description of the medical information to be disclosed, 45 C.F.R. § 164.508(c)(1)(i); failed to state the individuals or organizations authorized to disclose the . . . medical records, 45 C.F.R. § 164.508(c)(1)(ii); and failed to specify the type of information authorized to be used or disclosed, 45 C.F.R. § 164.508(c)(1)(iv).

Id. We thus concluded that the medical authorization the Stevens plaintiff provided “was woefully deficient,” had “numerous and significant” errors and omissions, and that, because of these deficiencies, the “[d]efendants were not authorized to receive any of the Plaintiff’s records.” Id. Nevertheless, we cautioned that “[a] plaintiff’s less-than-perfect compliance with [Section 121(a)(2)(E)]” will not always “derail a healthcare liability claim” because “[n]on-substantive errors and omissions will not always prejudice defendants by preventing them from obtaining a plaintiff’s relevant medical records.”⁷ Id. at 555. But we concluded that, “[a]s a result of multiple errors,” the Stevens plaintiff “failed to substantially comply with the requirements of [Section 121(a)(2)(E)].” Id. at 556.

Tennessee courts have now applied Stevens for more than six years, yet “Tennessee law is less than settled concerning the question of substantial compliance[,]” particularly with respect to Section 121(a)(2)(E). Rush v. Jackson Surgical Assocs. PA, No. W2016-01289-COA-R3-CV, 2017 WL 564887, at *4-5 (Tenn. Ct. App. Feb. 13, 2017). For example, in some cases, prejudice has been treated as a separate independent element of analysis, in addition to substantial compliance. See, e.g., Buckman v. Mountain States Health Alliance, 570 S.W.3d 229, 238-39 (Tenn. Ct. App. 2018) (concluding that the plaintiff failed to substantially comply with subsection (a)(2)(E) and also concluding “that the defendants were prejudiced” by the plaintiff’s noncompliance), perm. app. denied (Tenn. Nov. 15, 2018). In other cases, prejudice has been treated as a consideration relevant to the determination of whether a plaintiff has substantially complied with Section 121(a)(2)(E), and not as a separate and independent analytical element. See, e.g., Lawson v. Knoxville Dermatology Grp., P.C., 544 S.W.3d 704, 713 (Tenn. Ct. App. 2017) (concluding that the plaintiff failed to substantially comply with

⁷ For an example of an imperfect but substantially compliant medical authorization form, consult Hamilton v. Abercrombie Radiological Consultants, Inc., E2014-003433-COA-R3-CV, 2014 WL 7117802 (Tenn. Ct. App. Dec. 15, 2014), perm. app. denied (Tenn. May 15, 2015).

Section 121(a)(2)(E) where errors in the authorization prejudiced defendants), perm. app. denied (Tenn. Nov. 16, 2017); Hunt v. Nair, No. E2014-01261-COA-R9-CV, 2015 WL 5657083, at *10-12 (Tenn. Ct. App. Sept. 25, 2015) (concluding that plaintiffs substantially complied with Section 121(a)(2)(E) where non-substantive errors in the HIPAA authorizations did not prejudice the defendants), perm. app. denied (Tenn. Jan. 21, 2015).

We take this opportunity to clarify the role of prejudice in a court’s determination of whether a plaintiff in a health care liability action has substantially complied with Section 121. We reaffirm Stevens and hold that prejudice is not a separate and independent analytical element; rather, as Stevens explained, prejudice is a consideration relevant to determining whether a plaintiff has substantially complied. Stevens, 418 S.W.3d at 556 (stating that whether a plaintiff “has substantially complied with a statutory [content] requirement, a reviewing court should consider the extent and significance of the plaintiff’s errors and omissions and whether the defendant was prejudiced by the plaintiff’s noncompliance”). Prejudice, or the absence of prejudice, is especially relevant to evaluating the extent and significance of the plaintiff’s noncompliance. If a plaintiff’s noncompliance with Section 121 frustrates or interferes with the purposes of Section 121 or prevents the defendant from receiving a benefit Section 121 confers, then the plaintiff likely has not substantially complied with Section 121. See id. at 563 (noting that the focus should be “on the extent of the shortcomings and whether those shortcomings have frustrated the purpose of the statute or caused prejudice to the adversary party”). On the other hand, if the plaintiff’s noncompliance neither frustrates or interferes with the purposes of Section 121 nor prevents a defendant from receiving a benefit the statute confers, then a court is more likely to determine that the plaintiff has substantially complied.

We also take this opportunity to clarify the burdens each party bears when seeking to establish, or to challenge, compliance with Section 121. We adopt and apply the burden-shifting approach articulated in Myers v. AMISUB (SFH), Inc., 382 S.W.3d at 307. By statute, a health care liability plaintiff bears the initial burden of establishing compliance with Section 121 by stating in the pleadings and providing “the documentation specified in subdivision (a)(2),” or of alleging “extraordinary cause” for any noncompliance. Tenn. Code Ann. § 29-26-121(b). A defendant wishing to challenge a plaintiff’s compliance with Section 121(a)(2) must file a 12.02(6) motion to dismiss for failure to state a claim.⁸ Myers, 382 S.W.3d at 307. The defense motion must describe

⁸ If proof outside the pleadings is submitted and considered by the trial court, the motion must be treated as a motion for summary judgment. See Tenn. R. Civ. P. 12.02.

“how the plaintiff has failed to comply with [Section 121] by referencing specific omissions,” id., and by explaining “the extent and significance of the plaintiff’s errors and omissions and whether the defendant was prejudiced by the plaintiff’s noncompliance,” Stevens, 418 S.W.3d at 556. A defendant may demonstrate that the noncompliance resulted in prejudice by explaining—for example—how the noncompliance frustrated or interfered with the purposes of Section 121 or deprived the defendant of a benefit Section 121 confers. One means of satisfying this burden is by alleging that the plaintiff’s Section 121(a)(2)(E) medical authorization lacks one or more of the six core elements required by federal law for HIPAA compliance. Under federal law, a medical authorization is not HIPAA compliant if “[t]he authorization has not been filled out completely, with respect to” a core element. 45 C.F.R. § 164.508(b)(2)(ii). Without a HIPAA compliant medical authorization, a defendant would ordinarily be deprived of a benefit Section 121 confers, as it declares that “[a]ll parties . . . shall be entitled to obtain complete copies of the claimant’s medical records from any other provider receiving notice.” Tenn. Code Ann. § 29-26-121(d)(1). Although defendants must explain how they were prejudiced by noncompliance, defendants need not “test” incomplete and facially noncompliant medical authorizations. As we recognized in Stevens, obtaining medical records with a HIPAA noncompliant medical authorization would violate federal regulations and could result in the imposition of severe penalties. Stevens, 418 S.W.3d at 565 n.6; see also Woodruff ex rel. Cockrell v. Walker, 542 S.W.3d 486, 499 (Tenn. Ct. App. 2017) (“Because the penalties imposed on entities that wrongfully disclose or obtain private health information in violation of HIPAA are severe, the sufficiency of the plaintiffs’ medical authorizations is imperative.”), perm. app. denied (Tenn. Oct. 6, 2017); J.A.C. ex rel. Carter v. Methodist Healthcare Memphis Hosps., 542 S.W.3d 502, 514-15 (Tenn. Ct. App. 2016) (stating that a health care liability defendant has no duty to assist a plaintiff to achieve compliance with Section 121 or to test the validity of a medical authorization that is facially lacking a core element required for HIPAA compliance); Dolman v. Donovan, No. W2015-00392-COA-R3-CV, 2015 WL 9315565, at *5 (Tenn. Ct. App. Dec. 23, 2015) (rejecting the plaintiffs’ argument that the medical providers could not have been prejudiced because they never attempted to obtain medical records with the deficient medical authorization provided), perm. app. denied (Tenn. May 6, 2016). As we emphasized in Stevens, plaintiffs, not defendants, are “responsible for complying with the requirements of [Section 121].” Stevens, 418 S.W.3d at 559.

Once a defendant files a motion that satisfies the foregoing prima facie showing, the plaintiff then bears the burden of establishing substantial compliance with Section 121, which includes the burden of demonstrating that the noncompliance did not prejudice the defense. Rye, 477 S.W.3d at 264-65; see also Moreno v. City of Clarksville, 479 S.W.3d 795, 802 (Tenn. 2015) (citations omitted) (stating that once the City established a prima facie statute of limitations defense, the plaintiff bore the burden of establishing an exception to the defense); Benton v. Snyder, 825 S.W.2d 409, 414

(Tenn. 1992) (citations omitted) (same). The plaintiff “may not rest upon the mere allegations or denials of [its] pleading,” but must respond, and by affidavits or another means provided in Tennessee Rule 56, “set forth specific facts” demonstrating that the noncompliance did not prejudice the defense. Rye, 477 S.W.3d at 265. Defendants have no obligation to aid plaintiffs in meeting this burden, and defendants need not notify plaintiffs that a medical authorization lacks one or more of the six core elements federal law requires for HIPAA compliance. See Stevens, 418 S.W.3d at 559 (rejecting the argument that the defendant should have notified the plaintiff of the noncompliance with Section 121 so that the plaintiff could have remedied the problem).⁹

Applying this analysis to the undisputed facts in the record on appeal, we conclude that the Plaintiffs failed to substantially comply with Section 121(a)(2)(E). Like the medical authorization in Stevens, the Plaintiffs’ medical authorizations lacked three of the core elements required by federal law for HIPAA compliance. The Plaintiffs’ medical authorizations failed to include: (1) “[t]he name or other specific identification of the person(s), or class of persons authorized to make the requested use or disclosure[s,]” see 45 C.F.R. § 164.508(c)(1)(ii); (2) “[a]n expiration date or an expiration event that relates to the individual or the purpose of the use or disclosure[.]” see 45 C.F.R. § 164.508(c)(1)(v); and (3) “[i]f the authorization is signed by a personal representative of the individual, a description of such representative’s authority to act for the individual must also be provided[.]” see 45 C.F.R. § 164.508(c)(1)(vi). Given these omissions, the trial court correctly found that the medical authorizations were “useless” to the Defendants. 45 C.F.R § 164.508(b)(2)(ii) (stating that a medical authorization lacking a core element is not valid).

The Plaintiffs failed to respond to the Defendants’ prima facie showing and instead rested on the allegations and arguments in their pleadings, specifically, that the Defendants were not prejudiced by the noncompliance because the Plaintiffs and the Hospital Defendants had engaged in settlement negotiations several months before the Plaintiffs filed the lawsuit and that the Hospital Defendants already had all of the decedent’s relevant medical records. The Hospital Defendants have never conceded that they were not prejudiced by the Plaintiffs’ failure to comply with Section 121(a)(2)(E), as

⁹ As one commentator cautioned not long after Section 121(a)(2) was adopted:

There is no penalty for giving more information than required by statute in the notice letter. *However, those who fail to give the information required by the statute are at risk for an assertion that the notice is defective and does not operate to extend the statute of limitations. Thus, counsel may wish to use a checklist to ensure that each letter sent to a health care provider complies with the notice statute.*

Day, supra, at 15 (emphasis added).

the hospital did in the case on which the Plaintiffs rely to support their argument. See Hughes, 2015 WL 3562733. To the contrary, the Hospital Defendants have consistently argued that they were prejudiced because, without an authorization allowing them to request records from Dr. Karl, they were unable to fully investigate the case during the pre-suit notice period. In any event, settlement negotiations are not a substitute for a HIPAA compliant medical authorization as required by Section 121(a)(2)(E). Cf. Foster, 467 S.W.3d at 916 (holding that plaintiffs must provide pre-suit notice each time a complaint is filed and that the pre-suit notice filed before the first complaint was not sufficient when the plaintiff filed a second complaint pursuant to the savings statute). As to Dr. Karl, the Plaintiffs have asserted that he had access to all the decedent's medical records because he was either an employee or ostensible agent of Rolling Hills. Again, Dr. Karl has not admitted these allegations, and he introduced correspondence showing that he attempted to use the Plaintiffs' noncompliant medical authorization without success. The Plaintiffs simply have failed to point to specific facts in the record to satisfy their burden of showing that the Defendants were not prejudiced by their noncompliance. The record on appeal instead supports the Defendants' arguments that the Plaintiffs' noncompliance precluded them from receiving the benefits Section 121(a)(2)(E) and (d) were intended to confer by preventing them from obtaining the decedent's medical records from all other providers named as defendants. See Parks v. Walker, 585 S.W.3d 895, 900 (Tenn. Ct. App. 2018) (holding that a medical authorization lacking core elements required by federal law for HIPAA compliance was not substantially compliant with Section 121(a)(2)(E)), perm. app. denied (Tenn. Mar. 27, 2019); Buckman, 570 S.W.3d at 239 (same); J.A.C., 542 S.W.3d at 513 (same).

The trial court here also noted that the Plaintiffs failed to make any showing of extraordinary cause to excuse their noncompliance with Section 121(a)(2)(E). The trial court addressed this issue, even though the Plaintiffs did not assert extraordinary cause at all in their responses to the Defendants' motions to dismiss. Rather, the Plaintiffs resisted the Defendants' motions by asserting that they had substantially complied with Section 121. The Plaintiffs have raised extraordinary cause in passing in their briefs in the Court of Appeals and in this Court; but, as a general rule, "issues raised for the first time on appeal are waived." State v. Rowland, 520 S.W.3d 542, 545 (Tenn. 2017) (citing Fayne v. Vincent, 301 S.W.3d 162, 171 (Tenn. 2009)). This general rule of waiver applies here to the Plaintiffs' assertion that extraordinary cause excused their noncompliance.

Accordingly, we conclude that the pre-suit notice the Plaintiffs provided before filing their first lawsuit failed to substantially comply with Section 121(a)(2)(E). Therefore, the Plaintiffs were not entitled to the 120-day extension of the statute of limitations and their first lawsuit was untimely filed. Because their first lawsuit was not timely filed, the Plaintiffs were not entitled to rely on the savings statute to establish the timeliness of this second lawsuit. Accordingly, the trial court correctly held that the Plaintiffs' lawsuit is time-barred.

IV. Waived Issue and Separate Opinion

In their brief to this Court, the Plaintiffs also assert that, even if they failed to substantially comply with Section 121(a)(2), they were still entitled to the 120-day extension of the statute of limitations provided in Section 121(c) because that extension is contingent upon a plaintiff's compliance with Section 121(a)(2)(B) not upon a plaintiff's compliance with Section 121(a)(2). The Plaintiffs recognize that this argument is inconsistent with several prior appellate court decisions, citing Stevens, 418 S.W.3d at 560; J.A.C., 542 S.W.3d at 512; Dolman, 2015 WL 9315565, at *3; and Roberts v. Prill, E2013-02202-COA-R3-CV, 2014 WL 2921930, at *1 (Tenn. Ct. App. June 26, 2014), but the Plaintiffs assert that these decisions failed to analyze properly the language of Section 121(c). The Plaintiffs failed to raise this issue in either the trial court or the Court of Appeals. "Issues not raised in the trial court or in the intermediate appellate courts may be deemed waived when presented to this Court." Hodge v. Craig, 382 S.W.3d 325, 334 n.3 (Tenn. 2012) (citing Brown v. Roland, 357 S.W.3d 614, 620 (Tenn. 2012); In re Adoption of E.N.R., 42 S.W.3d 26, 32 (Tenn. 2001); Alexander v. Armentrout, 24 S.W.3d 267, 273 (Tenn. 2000)); see also Harmon v. Hickman Cmty. Healthcare Servs., Inc., 594 S.W.3d 297, 300-301 (Tenn. 2020) (deeming waived several issues raised for the first time in this Court). We conclude that the Plaintiffs have waived this issue.

Inexplicably, Justice Kirby refuses to deem the Plaintiffs' new issue waived in her separate concurring in part and dissenting in part opinion and instead declares that the Defendants waived the defense of waiver. In Justice Kirby's circular analysis, the Defendants are at fault for not asserting waiver when the Plaintiffs raised an issue for the first time in their brief to this Court. Of course, the Plaintiffs have not argued that the Defendants waived the waiver defense (which presumably would mean, under Justice Kirby's analysis, that the Plaintiffs waived the argument that the Defendants waived the waiver defense). Nevertheless, Justice Kirby makes that declaration—that the Defendants waived the waiver defense—and then proceeds to address the merits of the issue the Plaintiffs have plainly waived. Conspicuous by its absence is any citation to authority supporting Justice Kirby's declaration that the Defendants waived the waiver defense. More importantly, Justice Kirby acknowledges that this Court's authority and discretion to deem an issue waived exists independent of a litigant's assertion of the defense. We exercise that authority without hesitation here, where the record on appeal is a textbook example of waiver. This record leaves no doubt that the Plaintiffs failed to preserve and raise in the courts below the issue Justice Kirby addresses on the merits and shows that the Plaintiffs first raised it in this Court. Moreover, only three months ago Justice Kirby authored an opinion that applied waiver in almost identical circumstances. See Harmon, 594 S.W.3d at 300-301 ("In Plaintiffs' brief to this Court, they seek to raise several additional issues. Most of these arguments were not made to either the trial court or the Court of Appeals. We deem these issues waived. 'Issues not raised in the trial

court or in the intermediate appellate courts may be deemed waived when presented to this Court.” (quoting Hodge, 382 S.W.3d at 334)).

In any event, notwithstanding the fundamental principle of waiver, Justice Kirby addresses the issue on the merits, faults the Court of Appeals (and presumably this Court as well as it denied applications seeking review of many of the intermediate appellate court decisions she now deems erroneous), and asserts that the Court of Appeals has frustrated the General Assembly’s intent by construing Section 121 as requiring plaintiffs to comply strictly with Section 121(a)(1) and substantially comply with Section 121(a)(2) to obtain a 120-day extension of the statute of limitations. Because the issue is waived, we need not expressly rebut each of Justice Kirby’s assertions. We are, however, constrained to make three observations.

First, Justice Kirby’s statutory analysis renders Section 121(a)(2) meaningless and is inconsistent with the understanding of the statute’s meaning by persons who were familiar with the 2009 amendments. See, e.g., Day, supra, at 15 (“There is no penalty for giving more information than required by statute in the notice letter. However, those who fail to give the information required by the statute are at risk for an assertion that the notice is defective and does not operate to extend the statute of limitations.”).

Second, Justice Kirby mischaracterizes in footnote 7 this Court’s decision in Stevens. This Court in Stevens dismissed the lawsuit without prejudice and did not decide whether the dismissal without prejudice would, as a practical matter, mean the plaintiff’s claim was time-barred because “the trial court did not reach this issue.” Stevens, 418 S.W.3d at 560.

Third, and finally, Justice Kirby’s assertion that courts have misconstrued Section 121 and frustrated the General Assembly’s intent is refuted by the fact that in the eleven years since its enactment the General Assembly has not amended the statute to abrogate these allegedly erroneous judicial decisions. Coffee Cnty. Bd. of Ed. v. City of Tullahoma, 574 S.W.3d 832, 847 (Tenn. 2019) (“[L]egislative inaction following a contemporaneous and practical interpretation of a statute is considered persuasive evidence of the Legislature’s intent to adopt that interpretation.” (Citations omitted)); Freeman Indus. v. Eastman Chem. Co., 172 S.W.3d 512, 519 (Tenn. 2005) (“[T]he legislature’s failure to express disapproval of a judicial construction of a statute is persuasive evidence of legislative adoption of the judicial construction.” (Internal quotation marks and citations omitted)).

V. Conclusion

For the reasons stated herein, we reverse the judgment of the Court of Appeals and reinstate the judgment of the trial court dismissing this lawsuit as time-barred. Costs on appeal are taxed to the Plaintiffs for which execution may issue if necessary.

CORNELIA A. CLARK, JUSTICE