IN THE SUPREME COURT OF FLORIDA
CASE NO.: SC15-2180

JEAN CHARLES, JR., as next Friend and duly appointed Guardian of his sister, MARIE CHARLES, and her minor children, ANGEL ALSTON, and JAZMIN HOUSTON, minors, and PERVIN ALSTON,

Appellants,

v.

SOUTHERN BAPTIST HOSPITAL OF FLORIDA, INC. d/b/a Baptist Medical Center-South, KRISTIN FERNANDEZ, D.O., YUVAL Z. NAOT, M.D., SAFEER A. ASHRAF, M.D., INTEGRATED COMMUNITY ONCOLOGY NETWORK, LLC, a Florida limited liability corporation, ANDREW NAMEN, M.D., GREGORY J. SENGSTOCK, M.D., JOHN D. PENNINGTON, M.D., and EUGENE R. BEBEAU, M.D.,

Appellees.
_____ /

L.T. Case Nos.: 1D15-0109
2012-CA-002677

ON APPEAL FROM THE DISTRICT COURT, FIRST DISTRICT, STATE OF FLORIDA

SUPPLEMENTAL BRIEF OF APPELLANTS

COKER, SCHICKEL, SORENSON, POSGAY, CAMERLENGO, & IRACKI

John J. Schickel
Florida Bar No. 0158169
Howard C. Coker
Florida Bar No. 141540
Charles A. Sorenson
Florida Bar No. 0202606
JJS@cokerlaw.com
HCC@cokerlaw.com
CAS@cokerlaw.com
RMS@cokerlaw.com
136 East Bay St.
Jacksonville, Florida 32202
Telephone: (904) 356-6071
Facsimile: (904) 353-2425

Trial Counsel for Appellants Jean Charles, Jr., as next friend and duly appointed Guardian of his sister, Marie Charles, and her minor children, Angel Alston and Jazmin Houston, minors, and Pervin Alston

CREED & GOWDY, P.A.

Bryan S. Gowdy
Florida Bar No. 0176631
bgowdy@appellate-firm.com
filings@appellate-firm.com
865 May Street
Jacksonville, Florida 32204
Telephone: (904) 350-0075
Facsimile: (904) 503-0441

Attorney for Appellants Jean Charles, Jr., as next friend and duly appointed Guardian of his sister, Marie Charles, and her minor children, Angel Alston and Jazmin Houston, minors, and Pervin Alston

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ARGUMENT

This Court has asked for supplemental briefing to address the Guidance on the Patient Safety and Quality Improvement Act of 2005, 81 Fed. Reg. 32655 (codified at 42 C.F.R. Part 3), issued by the U.S. Department of Health and Human Services (HHS) on May 24, 2016 (2016 Guidance). Two points bear emphasis. First, the 2016 Guidance confirms what Appellants, the Charles family, have argued all along. Second, this Court should defer to the 2016 Guidance.

I. The 2016 Guidance validates the Charles family's arguments.

On the critical issues argued in the parties' briefs, the 2016 Guidance fully corroborates the Charles family's arguments and squarely rejects Baptist's arguments. Herein, we recite those critical issues, state the positions of the parties and HHS, and then show how HHS has adopted the Charles family's position.

Issue #1: Whether information that must be collected, maintained, or developed for state-law reporting and recordkeeping requirements may be privileged patient safety work product (PSWP) under the PSQIA?

a. Charles family's position: No. (IB 36-40.)

b. Baptist's position: Yes. (AB 23.)

c. HHS's position: No.

In the 2016 Guidance, HHS expressly rejects Baptist's position:

- "The intent of the system established by the [PSQIA] is . . . not to protect records created through providers' mandatory information collection activities. For example, a provider may have an external obligation to maintain certain records about serious adverse events

that result in patient harm. The document the provider prepares to meet its requirement about such adverse events is not PSWP. . . . [T]he [PSQIA] was not designed to prevent patients who believed they were harmed from obtaining the records about their care that they were able to obtain prior to the enactment of the [PSQIA]." 2016 Guidance, 81 Fed. Reg. at 32655-56.

- "The [PSQIA] and [HHS's 2008] Rule . . . exclude from the PSWP definition 'information that is collected, maintained, or developed separately, or exists separately, from a patient safety evaluation system [(PSES)].' Put another way, information prepared for purposes other than reporting to a PSO is not PSWP under the reporting pathway." *Id.* at 32656.

- "[T]he [PSQIA] does not permit providers to use the privilege and confidentiality protections for PSWP to shield records required by external recordkeeping or reporting requirements." *Id.* at 32657

- "[The PSQIA] was not intended to protect records generated or maintained as part of providers' existing mandatory information collection activities. As stated in the [2008] Preamble, '[HHS]does not believe that the patient safety evaluation system enables providers to avoid transparency. . . . [T]he [PSQIA] and the [2008 Rule] have carefully assured that information generally available today remains available, such as medical records, original provider documents, and business records.'" *Id.*

<u>Issue #2</u>: Whether Baptist may satisfy state-law recordkeeping requirements with information that is PSWP?

a. Charles family's position: No. (IB at 5 & n. 3, 38; RB at 5-6.)

b. Baptist's position: Yes. (AB at 6-7, 23-27.)

c. HHS's position: No.

HHS has squarely rejected Baptist's position on this issue:

- "External obligations include . . . mandatory requirements placed upon providers by Federal and state health regulatory agencies. Both the [2008 Rule] and Preamble clearly state that PSWP cannot be used to satisfy such external obligations. As the [PSQIA] states

> more than once, these external obligations must be met with information that is not [PSWP]. . . . In the [2008] Preamble, HHS repeatedly stated that PSWP cannot be used to fulfill external obligations."2016 Guidance, 81 Fed. Reg. at 32657.

- "HHS reiterates that any external reporting or recordkeeping obligations—whether they require a provider to report certain information, maintain specific records, or operate a separate system—cannot be met with PSWP. We also clarify that any information that is prepared to meet any Federal, state, or local health oversight agency requirements is not PSWP." *Id.*

Issue #3: Whether, in violation of the PSQIA, Baptist has unlawfully merged its mandatory data collection and reporting requirements under Florida law with its voluntary reporting system under the PSQIA?

a. Charles family's position: Yes. (IB at 25, 38, 41-42.)

b. Baptist's position: No. (AB at 19.)

c. HHS's position: Yes.

HHS's 2016 Guidance warns Baptist that its current practice of merging its state recordkeeping systems with its federal PSE system is unlawful:

> [W]e are concerned . . . that some providers may be attempting to misuse the [PSQIA] protections to avoid their external obligations—in particular, to circumvent Federal or state regulatory obligations. . . .[S]ome providers with recordkeeping or record maintenance requirements appear to be maintaining the required records only in their [PSE system] and then refusing to disclose the records, asserting that the records in their [PSE system] fulfill the applicable regulatory requirements while at the same time maintaining that the records are privileged and confidential PSWP. . . .The [PSQIA] was not intended to give providers such methods to evade their regulatory obligations.

2016 Guidance, 81 Fed. Reg. at 32657-58. Further, HHS has warned Baptist that its practice of maintaining state-mandated incident reports solely in its PSE system is

"improper" and a "misuse" of the PSQIA: "We note that it would be improper to maintain records collected for external reporting purposes solely within a PSES because this scenario would be a misuse of a PSES." *Id.* at 32658.

Indeed, the 2016 Guidance is clear that Baptist must maintain state-mandated information separately from its privileged PSES database: "[W]e reemphasize that where records are mandated by a Federal or State law requirement or other external obligation, they are not PSWP. Thus, a provider should maintain at least two systems or spaces: A PSES for PSWP and a separate place where it maintains records for external obligations." *Id.* at 32659 (emphasis added).

II. This Court should defer to the 2016 Guidance, which was developed as the result of a request of the U.S. Supreme Court.

Baptist likely will argue this Court should give no deference to the 2016 Guidance for a variety of misplaced reasons, including: (i) it was not subject to a notice-and-comment period; (ii) it is purportedly a mere litigation position; and (iii) it is allegedly inconsistent with the PSQIA and HHS's 2008 Rule. These arguments are without merit. *Infra* Argument II.B., at 8. Preliminarily, however, we explain how the 2016 Guidance was developed. *Infra* Argument II.A., at 4.

A. HHS developed the 2016 Guidance as a result of a request of the U.S. Supreme Court directed at the federal Executive Branch.

HHS's 2016 Guidance arises out of a petition for writ of certiorari filed in the U.S. Supreme Court by medical providers. Those providers sought to overturn the

controlling opinion of the Supreme Court of Kentucky in *Tibbs v. Bunnell*, 448 S.W.3d 796 (Ky. 2014).[1] In this very case, the First District adopted the reasoning of the *Tibbs* dissent. (R. 477.) Many of the same amici who are supporting Baptist in this case also filed amicus briefs in the U.S. Supreme Court urging the Court to reverse *Tibbs*. *See supra* note 1. Critically, however, the United States Government never was a party to the *Tibbs* litigation, nor did it seek on its own initiative to appear as an amicus in *Tibbs*. *See id.*; *Tibbs*, 448 S.W.3d at 796. Instead, as Baptist correctly informed this Court, the U.S. Supreme Court in October 2015 asked the U.S. Solicitor General for the Government's views on the *Tibbs* petition. (AB 45.)

An understanding of this process – which is referred to as CVSG, or "calling for the views of the Solicitor General" – will reinforce why the 2016 Guidance should be accorded deference. The Court invokes the CVSG process in cases in which the Government is not a litigant. Drew S. Days, III, *The Solicitor General and the American Legal Ideal*, 49 SMU L. Rev. 73, 79 (1995). Thus, as one former Solicitor General has written, in the CVSG process, the Court "is not seeking the advice of an advocate or a partisan, but rather of an officer of th[e] [C]ourt

[1] The docket for *Tibbs v. Bunnell*, Case No. 14-1140, is on the U.S. Supreme Court's website. https://www.supremecourt.gov/search.aspx?filename=/docketfiles/14-1140.htm (last visited July 21, 2016). All the briefs and other papers filed in U.S. Supreme Court are located at SCOTUSblog. http://www.scotusblog.com/case-files/cases/tibbs-v-bunnell/ (last visited July 21, 2016).

committed to providing his best judgment with respect to the matter at issue." *Id.* Similarly, Justice Ginsberg has described the CVSG process as follows:

> The Solicitor General . . . represent[s] the United States in the Supreme Court. When we call for the Solicitor's views in a case in which the United States is not a party, the Solicitor acts as a true friend of the Court; after consulting with federal executive agencies and officers with relevant expertise, he offers his views on the importance or unimportance of the question presented to the sound development of federal law.

Ruth Bader Ginsburg, *Workways of the Supreme Court Thomas Jefferson School of Law San Diego February 6, 2003*, 25 T. Jefferson L. Rev. 517, 519 (2003). Four justices must concur to invoke the CVSG process. Patricia A. Millett, *"We're Your Government and We're Here to Help": Obtaining Amicus Support from the Federal Government in Supreme Court Cases*, 10 J. App. Prac. & Process 209, 212 (2009).

The Supreme Court started the CVSG process in *Tibbs* in October 2015. *See supra* note 1. Seven months later in May 2016, the Government submitted an amicus brief in which the Solicitor General presented the Government's official interpretation of the PSQIA, the same federal statute at issue in this case.[2] *See id.* On the same day it submitted its amicus brief, the Government, via the HHS, issued its 2016 Guidance. *See id.*; 81 Fed. Reg. 32655.

[2] This Court, at Baptist's urging, has declined to review the Government's brief in *Tibbs*. (6-30-2016 Order.) But, under federal law, a federal agency's legal brief is due some level of judicial deference. *See, e.g., Chase Bank USA, N.A. v. McCoy*, 562 U.S. 195, 208 (2011). Thus, this Court should review the Government's brief.

While the 2016 Guidance may not have been subject to public comment, medical providers and others had the opportunity to present their views to the Government before the 2016 Guidance was issued. During the seven-month CVSG period, counsel for the *Tibbs* parties, including the medical providers who filed the petition, almost certainly met at the Solicitor General's office with the lawyers from that office, as well as with HHS officials. *See* Millett, *supra*, 10 J. App. Prac. & Process at 216-18. At this meeting, counsel for the *Tibbs* medical providers would have presented their arguments on how to interpret and apply the PSQIA and the 2008 Rule. *See id.* at 218-23. The Government officials at the meeting would have tested the soundness of the providers' position with extensive questioning. *Id.*

One purpose of a CVSG meeting is to give the Government the opportunity to resolve the issue presented – without Supreme Court intervention – by formulating new agency guidance. *See id.* at 214 & n. 14, 221. ("The Solicitor General is . . . uniquely positioned to explain whether legislative or regulatory amendments –or other administrative measures that might independently resolve any problem created by the lower court's ruling – are planned, thereby making Supreme Court review arguably unnecessary."). That is precisely the option the Government chose here. Specifically, HHS issued the 2016 Guidance to clarify the ambiguities, if any, in HHS's prior guidance (the 2008 Rule and Preamble) and the PSQIA itself. 81 Fed. Reg. 32655. Shortly thereafter, the U.S. Supreme Court denied the *Tibbs* petition.

See Tibbs v. Bunnell, Case No. 14-1140, 2016 WL 3461621 (U.S. June 27, 2016). For the reason argued next, this Court should defer to the 2016 Guidance.

B. The 2016 Guidance demands deference from this Court.

This Court should defer to HHS's 2016 Guidance. Granted, because the 2016 Guidance was issued without a notice-and-comment period, *Chevron*[3] deference does not apply to the 2016 Guidance, *United States v. Mead Corp.*, 533 U.S. 218, 230 (2001), but *Chevron* may still apply to the 2008 Rule, which was subject to a notice-and-comment period (IB 30-31 & n.14).

More importantly, however, *Chevron* is not the sole form of judicial deference. *See Mead*, 533 U.S. at 234 (agreeing that *Chevron* did not apply, but holding that the lack of *Chevron* deference did not "place [the agency's interpretation] outside the pale of any deference whatever"); *see also Wos v. E.M.A. ex rel. Johnson*, 133 S. Ct. 1391, 1403 (2013) (Breyer, J. concurring) (listing the various categories of non-*Chevron* judicial deference). For example, even without *Chevron* deference, an agency's interpretation of a statute it administers is "entitled to respect" under *Skidmore v. Swift & Co.*, 323 U.S. 134 (1944). *See Christensen v. Harris Cty.*, 529 U.S. 576, 587 (2000). The level of respect accorded under *Skidmore* depends on the agency's care, consistency, formality, and relative expertness, and the persuasiveness of the agency's position. *Mead*, 533 U.S. at 228.

[3] *Chevron, U.S.A., Inc. v. Natural Res. Def. Council, Inc.*, 467 U.S. 837 (1984).

Skidmore deference recognizes the agency's "specialized experience" and "the value of uniformity . . . [that] a national law requires." *Id.* at 234-35 (internal quotations omitted). These considerations should weigh heavily and counsel judicial deference to the 2016 Guidance. HHS is charged with regulating hospitals like Baptist and ensuring their compliance with a host of federal statutes. *See http://www.hhs.gov/regulations/* (last visited July 20, 2016). HHS, unlike judges, has specialized experience in how hospitals operate. And judicial deference to HHS's interpretation will ensure the PSQIA is implemented uniformly throughout the nation, not one way in Florida and another way in Kentucky and the other 48 states.

Auer deference is another applicable non-*Chevron* doctrine. *See Auer v. Robbins*, 519 U.S. 415 (1997); *Bowles v. Seminole Rock & Sand Co.*, 325 U.S. 410 (1945). The 2016 Guidance interprets and clarifies HHS's 2008 Rule. *See* 81 Fed. Reg. at 32656. Federal agencies may issue such interpretive rules without a notice-and-comment period, *Perez v. Mortgage Bankers Ass'n*, 135 S. Ct. 1199, 1203-04 (2015), and these rules "authoritatively" resolve ambiguities in an agency's regulations, *id.* at 1211 (Scalia, J. concurring) (citing *Auer*, 519 U.S. at 415). Stated another way, an agency's interpretation of its own regulation is "controlling" unless it is "plainly erroneous or inconsistent with the regulation." *Auer*, 519 U.S. at 461.

Baptist is wrong insofar as it argues the 2016 Guidance conflicts with the PSQIA and HHS's 2008 Rule and Preamble. The 2016 Guidance conflicts only with

Baptist's own distorted reading of these laws. With the 2016 Guidance, HHS has adopted the Charles family's interpretation and rejected Baptist's interpretation. That does not make the 2016 Guidance "plainly erroneous" or "inconsistent."

Deference under *Auer* is generally required even when the agency's interpretation is advanced in a legal brief. *Christopher v. SmithKline Beecham Corp.*, 132 S. Ct. 2156, 2166 (2012). The 2016 Guidance is neither "post hoc" nor "made for litigation" and thus is entitled to deference. This Court should not be misled by Baptist's reliance on distinguishable cases. For example, in *Christopher*, the Court declined *Auer* deference because the Government "changed course" by providing different reasons in amicus briefs filed in various courts. *Id.* at 2165-67. In contrast, here, the Government has filed, in conjunction with the 2016 Guidance, a single amicus brief in *Tibbs*, the only PSQIA case to reach a federal appellate court, and it has merely read the PSQIA and the 2008 Rule in the same manner that every court, except the First District, has read it. This is also not a case where HHS has failed to exercise "fair and considered judgment" or seeks to defend some past agency action, *cf. id.* at 2166-67, or where the Government's lawyer acted alone without agency input, *cf. Bowen v. Georgetown Univ. Hosp.*, 488 U.S. 204, 212 (1988).

In conclusion, the Court should agree with the 2016 Guidance and reverse.

Respectfully submitted,

CREED & GOWDY, P.A.
/s/ Bryan S. Gowdy

Bryan S. Gowdy
Florida Bar No.: 0176631
bgowdy@appellate-firm.com
filings@appellate-firm.com
865 May Street
Jacksonville, Florida 32204
Telephone: (904) 350-0075
Facsimile: (904) 503-0441
Attorney for Appellants Jean Charles, Jr., as next friend and duly appointed Guardian of his sister, Marie Charles, and her minor children, Angel Alston and Jazmin Houston, minors, and Pervin Alston

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that a true and correct copy of the foregoing has been furnished, via electronic mail, to the following on this 21st day of July, 2016:

Borden R. Hallowes
bhallowes@bellsouth.net
cshallowes@gmail.com
545 Oglethorpe Avenue, Suite 202
St. Simons Island, Georgia 31522
Trial Counsel for Plaintiffs/Appellants

Thomas S. Edwards, Jr.
tse@edwardsragatz.com
EDWARDS & RAGATZ, P.A.
501 Riverside Avenue, Suite 601
Jacksonville, Florida 32202
Trial Counsel for Plaintiffs/Appellants

Jack E. Holt, III
jeholtiii@growerketcham.com
ngallagher@growerketcham.com
enotice@growerketcham.com
GROWER, KETCHAM, RUTHERFORD, BRONSON, EIDE & TELAN, P.A.
Post Office Box 538065
Orlando, Florida 32853-8065
Attorney for Appellee Southern Baptist Hospital of Florida, Inc. d/b/a Baptist Medical Center South

John J. Schickel
JJS@cokerlaw.com
Howard C. Coker
HCC@cokerlaw.com
Charles A. Sorenson
CAS@cokerlaw.com
RMS@cokerlaw.com
COKER, SCHICKEL, SORENSON, POSGAY, CAMERLENGO & IRACKI
136 East Bay Street
Jacksonville, Florida 32202
Trial Counsel for Plaintiffs/Appellants

P. Scott Mitchell
smitchell@fmhslaw.com
Kathryn L. Hood
khood@fmhslaw.com
cmcrae@fmhslaw.com
FULLER, MITCHELL, HOOD & STEPHENS, LLC
2565 Barrington Circle
Tallahassee, Florida 32308
Trial Counsel for Defendants/ Appellee Yuval Z. Naot, M.D., Safeer A. Ashraf, M.D., and Integrated Community Oncology Network, LLC

William E. Kuntz
wkuntz@smithhulsey.com
Michael H. Harmon
mharmon@smithhulsey.com
Earl E. Googe, Jr.
egooge@smithhulsey.com
sjohnson@smithhulsey.com
khettinger@smithhulsey.com
SMITH HULSEY & BUSEY
225 Water Street, Suite 1800
Jacksonville, Florida 32202
Attorneys for Appellee Southern Baptist Hospital of Florida, Inc. d/b/a Baptist Medical Center South

John R. Saalfield
Duke Regan
saalfield.filings@saalfieldlaw.com
STOUDEMIRE & STONE, P.A.
245 Riverside Avenue, Suite 400
Jacksonville, Florida 32202
Trial Counsel for Defendant/ Appellee John D. Pennington, M.D

George N. Meros, Jr.
george.Meros@gray-robinson.com
Andy Bardos
andy.bardos@gray-robinson.com
charlene.roberts@gray-robinson.com
mwilkinson@gray-robinson.com
GRAY ROBINSON, P.A.
301 South Bronough Street, Suite 600
Tallahassee, Florida 32301
Attorneys for Appellee Southern Baptist Hospital of Florida, Inc. d/b/a Baptist Medical Center South

Jesse F. Suber
mmeservice@henryblaw.com
jpappas@henryblaw.com
HENRY, BUCHANAN, HUDSON, SUBER & CARTER, P.A.
2508 Barrington Circle
Tallahassee, Florida 32308
Trial Counsel for Defendant/Appellee Andrew Namen, M.D

W. Douglas Childs
dchilds@childslegalgroup.com
Linda M. Hester
lhester@childslegalgroup.com
pcreech@childslegalgroup.com
mowens@childslegalgroup.com
CHILDS, HESTER & LOVE, P.A.
1551 Atlantic Boulevard
Jacksonville, Florida 32207

Trial Counsel for Defendant/ Appellee Gregory J. Sengstock, M.D.

Christopher V. Carlyle, B.C.S.
ccarlyle@appellatelawfirm.com
served@appellatelawfirm.com
The Carlyle Appellate Law Firm
The Carlyle Building
1950 Laurel Manor Drive, Suite 130
The Villages, Florida 32162
Appellate Counsel for Amicus Curiae, Florida Consumer Action Network

George A Vaka
Nancy A Lauten
Richard N Asfar
gvaka@vakalaw.com
nlauten@vakalaw.com
rasfar@vakalaw.com
VAKA LAW GROUP, P.L.
777 S. Harbour Island Blvd., Ste. 300
Tampa, Florida 33602
Appellate Counsel for Amicus Curiae AARP Inc.

Andrew S. Bolin
asb@law-fla.com
BEYTIN, MCLAUGHLIN, MCLAUGHLIN, O'HARA, BOCCHINO & BOLIN
201 N. Franklin Street, Suite 2000
Tampa, Florida 33602
Appellate Counsel for Amicus Curiae, The Patient Safety Organization of Florida and ECRI Institute PSO

Elizabeth J. Campbell
ecampbell@lockelord.com
LOCKE LORD LLP
525 Okeechobee Blvd, Suite 1600
West Palm Beach, Florida 33401
Appellate Counsel for Amicus Curiae Alliance for Quality Improvement and Patient Safety

Katherine E. Giddings
Katherine.giddings@akerman.com
Kirk S. Davis
Kirk.davis@akerman.com
AKERMAN LLP
106 East College Avenue, Suite 1200
Tallahassee, Florida 32301
Counsel for Amicus Curiae, The Joint Commission

Kathleen T. Pankau
kpankau@jointcommission.org
One Renaissance Boulevard
Oakbrook Terrace, Illinois 60181
Counsel for Amicus Curiae, The Joint Commission

/s/ Bryan S. Gowdy
Attorney

CERTIFICATE OF COMPLIANCE

I HEREBY CERTIFY that the foregoing brief is in Times New Roman 14-point font and complies with the font requirements of Rule 9.210(a)(2), Florida Rules of Appellate Procedure.

/s/ Bryan S. Gowdy
Attorney