IN THE SUPREME COURT OF FLORIDA

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.
_____/

CASE NO.: SC15-2180
DCA Case No.: ID15-0109
L.T. Case No: 2012-CA-002677

AMICUS CURIAE BRIEF OF THE ALLIANCE FOR QUALITY IMPROVEMENT AND PATIENT SAFETY, INC. IN SUPPORT OF APPELLEE

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INTEREST OF THE AMICI

The Alliance for Quality Improvement and Patient Safety, Inc. ("Alliance") is a nonprofit national trade association. The Alliance is composed of over twenty-five Patient Safety Organizations ("PSOs") and their member providers, including hospitals, and healthcare organizations throughout the state of Florida. The Alliance's mission is to preserve the ability of PSOs to improve the quality of patient care through the privilege and confidentiality protections afforded by the Patient Safety and Quality Improvement Act of 2005 (42 U.S.C. § 299b-21 *et seq*.) ("PSQIA"). Accordingly, the Alliance has a great stake in the outcome of this appeal.

INTRODUCTION AND SUMMARY OF ARGUMENTS

The Alliance submits this brief in support of Appellee because a ruling in Appellants' favor would significantly undermine the PSQIA in Florida. According to the plain and ordinary terms of the PSQIA, the occurrence reports at issue in this case are protected patient safety work product because they were created to transfer to a patient safety organization, have the potential to improve patient safety and were maintained within Appellee Southern Baptist Hospital of Florida, Inc.'s ("Baptist") patient safety evaluation system. Moreover, to the extent Florida's Amendment 7 requires the production of patient safety work product, it is preempted by the PSQIA which must be broadly construed to achieve its remedial

purposes. Thus, the occurrence reports at issue in this case are plainly privileged.

Appellants' various attempts to avoid this inescapable conclusion are unpersuasive. Appellants' argument that state-mandated reports cannot be maintained within a Patient Safety Evaluation System as privileged must fail because patient safety work product can be used for any purpose within an entity. Federal protection of patient safety work product and Florida's mandate that state regulators be given access to internal risk management reports are complementary requirements. Providers can comply with state access requirements by taking advantage of the federal regulatory provision permitting them to maintain reports within their Patient Safety Evaluation Systems as privileged until the provider determines that the information is necessary to comply with a request for access by state regulators. Thus, Baptist is permitted to use the occurrence reports within its state-mandated internal risk management program.

ARGUMENT

I. The PSQIA Preempts Amendment 7 of the Florida Constitution to the Extent it is Construed to Compel the Production of Patient Safety Work Product

A. Congress Intended to Place Patient Safety Work Product Beyond the Reach of Regulators and Litigants to Encourage Self-Reporting and Critical Analysis Vital to Improving Patient Safety

In enacting the PSQIA, Congress sought to create a "learning environment" to improve patient safety and to counteract the culture of blame extant in the

litigation and regulatory processes. Congress explained,

> The committee finds that S.720, the "Patient Safety and Quality Improvement Act of 2003" will promote a learning environment that is needed to move beyond the existing culture of blame and punishment that suppresses information about health care errors to a "culture of safety" that focuses on information sharing, improved patient safety and quality and the prevention of future medical errors. The committee believes that it is important to shift the current focus from culpability to a new paradigm of error reduction and quality improvement.

S. REP. NO. 108-197 at p. 3.

State peer review protections, which Florida abandoned when it adopted Amendment 7, were found by Congress to be "inadequate to allow for the sharing of information to promote patient safety." S. 544 109th Cong. § 2(9) (March 8, 2005). The PSQIA created strong privilege and confidentiality protections for patient safety work product to encourage the reporting and analysis of errors and "near misses" by providers and PSOs free from the fear that these reports would be subject to discovery by regulators and litigants. S. REP. NO. 108-196 at p. 5. The Act does not protect all health care information from discovery; only patient safety work product. 42 U.S.C. § 299b-22(d).

The purpose of Amendment 7 "was to do away with existing restrictions on a patient's right to access a medical provider's history of adverse medical incidents and to provide a clear path to access those records." *Florida Hospital Waterman,*

Inc. v. Buster, 984 So. 2d 478, 489 (Fla. 2008). To the extent Amendment 7's reach encompasses patient safety work product in any particular case, there can be no state act more fundamentally at odds with Congress' philosophy and purpose in enacting the PSQIA. Contrary to Amici AARP's contention that Amendment 7 enhances the quality of health care by providing critical information to litigants and allowing patients to make informed decisions about their physician, Congress determined that neither of these purported benefits actually enhances health care. Both purported benefits are retrospective and narrow rather than the prospective systemic approach envisioned by Congress to avoid errors from occurring in the first place.

Nevertheless, Congress recognized that litigants need information to redress their injuries. For that reason, a patient's medical records, discharge records, billing records and other original provider records, as well as information maintained outside the Patient Safety Evaluation System, were excluded from the privilege. But Congress viewed the "culture of blame" as inhibiting, not enhancing, patient safety. Congress envisioned the cure to be a system in which providers, advised by PSOs, would collect and analyze data related to adverse events and then perform the self-critical analyses necessary to improve patient safety. Congress determined that ultimately individual patient safety would be found through systemic improvements led by providers and PSOs.

Congress was prompted to enact the PSQIA by data extrapolations suggesting that as many as 98,000 hospital patients lost their lives annually to preventable medical errors. *See Institute of Medicine, To Err is Human: Building a Safer Health System*, p. 1 (National Academy Press 1999); *See L. Leape, M.D., Institute of Medicine Error Figures Are Not Exaggerated, Journal of American Medical Association*, Vol. 284, No. 1, p. 95 (2000). Congress sees the privilege and confidentiality provisions of the PSQIA as the central components necessary to create the "culture of safety" and "learning environment" vital to preventing tens of thousands of deaths of American citizens every year. At the same time, Congress viewed the inadequacies of state peer review protections as inhibiting its goal to increase patient safety. In order to foster this goal, the privilege protection of the PSQIA, as a remedial measure designed to protect the public health, ought to be given its broadest interpretation consistent with its terms. The narrow view proffered by the Appellants would do nothing to improve patient safety and would ultimately discourage the widespread sharing of information the PSQIA was intended to promote.

A remedial statute is one enacted to correct a problem. *Campus Communications, Inc. v. Earnhardt*, 821 So. 2d 388, 396 (Fla. Ct. App. 5th Dist. 2002). Such a statute must be construed liberally "in favor of granting access to the remedy provided by the Legislature." *Golf Channel v. Jenkins*, 752 So. 2d 561,

565-566 (Fla. 2000). Remedial statutes should be interpreted broadly "to suppress the evil identified by the legislature, and to advance the remedy intended." *Connor v. Division of Elections*, 643 So. 2d 75, 76 (Fla. Ct. App. 1st Dist. 1994). Courts must never interpret a remedial statute strictly or narrowly so as to "thwart the intent of the Legislature." *E.A.R. v. State*, 4 So. 3d 614, 629 (Fla. 2009).

Broad protection of patient safety work product most assuredly has the potential to improve patient safety, health care quality and outcomes. "The breadth of data available to PSOs . . . will facilitate the identification and analysis of patterns of organization and behavior that can lead to errors." S. REP. NO. 108-196, at 10. Reliable information is necessary for patient safety organizations to perform their fundamental patient safety activities, which include the collection and analysis of patient safety work product. *See* 42 U.S.C. § 299b-21(5). Data indicating the type of incident reported, the time or shift when the incident occurred, the circumstances of the incident, whether harm resulted from the incident, the existence of an unsafe condition, and factors contributing to the incident known at the time of the initial report is invaluable in identifying areas or personnel requiring improvement or change. That same information examined after remedial measures are implemented may be used to evaluate the effectiveness of such measures.

The protection of patient safety work product is essential to enable PSOs to

perform core patient safety activities such as "undertak[ing] broader statistical pattern analyses" across multiple providers. S. REP. NO. 108-196, at 10. Ultimately, such information is to be reported to a network of patient safety databases, created by HHS, "to be used to analyze national and regional statistics, including trends and patterns of health care errors." 42 U.S.C. § 299b-23(c). This national database is to provide "an interactive evidence-based management resource" for members of the health care system. 42 U.S.C. § 299b-23(a). It is a system that Congress rightly determined will save lives.

If, as Appellants argue, a general state regulatory access provision is all that is required to nullify any claim of patient safety work product privilege, then there is no privilege. *See Upjohn Company v. United States*, 449 U.S. 383, 393 (1981) ("An uncertain privilege...is little better than no privilege at all."). The patient safety system that would survive would be a paper tiger, offering vanishingly narrow protections to any private entities that continued to participate. Indeed, the likely result of such a decision is the wholesale dismantling of the safety culture system Congress intended to create. *Tibbs v. Bunnell*, 448 S.W. 3d 796, 815 (Ky. 2014) (Abramson, J., dissenting) ("It is hard to imagine a holding more at odds with Congress's clear intent to foster provider trust in the patient safety system" . . . than permitting a trial court to "rummage through the provider's patient safety evaluation system and PSO submissions" in search of a state-mandated records . . .

and which "would completely undermine Congress's assurance to providers that they may participate in the patient safety system without fear of liability or harm to reputation."). A collapse of voluntary reporting would inevitably diminish the ability of health care systems to improve patient safety by identifying and correcting "faulty systems, processes, and conditions." This, in turn, would "undercut the Act's effectiveness in advancing patient safety" and may lead to increased patient injuries and deaths. See, *Id*. at 816.

B. There is No Presumption Against Preemption Because Congress has Traditionally Regulated Health Care Information and has Concluded that State Regulatory and Tort Systems Have Failed to Improve Patient Safety

Contrary to the contentions of the amici curiae who filed briefs in support of Appellants, the PSQIA unequivocally preempts Amendment 7 when the provision is employed in an attempt to obtain patient safety work product. Amicus curiae AARP contends that the PSQIA does not preempt Amendment 7 due to the state's "historic police powers" in the areas of public health and welfare. Brief of Amicus Curiae AARP at pp. 3-4. While the United States Supreme Court has applied a presumption against preemption of state laws in areas traditionally regulated by the states, *see Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485 (1996), that presumption simply does not exist where, as here, the statute contains a broad express preemption clause, the federal government has historically regulated in the field and the precipitating factor in enacting the federal statute is Congress' perception

of the inadequacies of state law.

Congressional intent is the "touchstone" for courts deciding a preemption issue. *Wyeth v. Levine*, 129 S.Ct. 1187, 1194 (2009). Congressional intent is determined by a plain reading of the statutory text. *Alteria Group, Inc. v. Good*, 555 U.S. 70, 76 (2008). There are two types of federal preemption: express and implied. *Alteria Group, Inc.*, 555 U.S. at 76-77. Express preemption occurs when the federal statute indicates by its terms that state law is superseded. *Id*.

The PSQIA contains express preemption language within its privilege and confidentiality provisions. 42 U.S.C. § 299b-22(a)-(b). Both provisions begin with the preamble: "[n]otwithstanding any federal, state or local law, and subject to [the exceptions of] subsection (c)," patient safety work product is declared privileged or confidential as the case may be." *Id*. The prefatory language clearly indicates that the provisions which follow supersede all other sources of law as they relate to the discoverability, using the broadest sense of the word, of patient safety work product. There can be no other meaning of such language. The statute also contains a meticulously crafted savings clause preserving those state laws providing greater protection for patient safety work product than PSQIA. *Id*. § 299b-22(g)(1). Such careful draftsmanship indicates a purpose to supersede state law.

Congress is also intimately involved in the regulation of healthcare

information. Since at least 1986, with the advent of the National Practitioner's Data Bank, and later the enactment of the Health Insurance Portability and Accountability Act ("HIPAA"), the federal government has been at the forefront in the regulation of healthcare information. See, 42 U.S.C. §§ 11101 *et seq.*; Health Insurance Portability and Accountability Act of 1996, Pub. L. No. 104-191 (1996) (codified as amended in scattered sections of U.S.C.).

Finally, in enacting the PSQIA, Congress found that state mandatory reporting systems and peer review protections were inadequate to promote patient safety, the overriding purpose of the legislation. S. 544, 109th Cong. §§ 2(a)(6)-(7), (9). State programs created "few incentives and many barriers for providers to collect and report information regarding patient safety." *Id*. at 7. Mandatory state reporting systems were believed to be "plague[d]" by underreporting and not effective in aggregating and analyzing information to lead to "broad system improvements." *Institute of Medicine, To Err Is Human: Building A Safer Health System 92-93 (Linda T. Kohn et als. eds., National Academy Press 2000)*.

Because the PSQIA contains a broad express preemption clause, the federal government has historically played a significant role in regulating the field, and Congress enacted the legislation to remedy perceived failures in state law, all of the tests for preemption are satisfied and any claimed presumption against preemption is easily overcome.

C. The PSQIA Preempts Amendment 7

Even where a Congressional act contains an express preemption clause, the court must still discern its meaning and define its scope. *Alteria Group, Inc.*, 555 U.S. at 76. The plain language of the PSQIA's preemption clause nullifying "any other provision of federal, state or local law" which would subject patient safety work product to compelled disclosure by state subpoena or court order or subject patient safety work product to discovery in a state civil matter undeniably extends to Amendment 7 to the extent it is employed to compel production of that privileged material. *See* U.S.C. § 299b-22(a).

In light of the PSQIA's savings clause, preserving those state laws offering greater protection to patient safety work product than the federal act, the question is whether Amendment 7 offers less protection from compelled disclosure of patient safety work product than does the PSQIA. Without belaboring the analysis, to the extent the application of Amendment 7 would require production of patient safety work product, it is superseded by the express language of the federal act because such disclosure would destroy the federal statute's privilege protections. *See* 42 U.S.C. § 299b-22(a). The only question remaining is whether the subject incident reports are patient safety work product.

II. The Subject Occurrence Reports are Privileged Patient Safety Work Product Whose Production Cannot Be Compelled By Court Order

The Appellants again press the same arguments that were rejected by the

First District Court of Appeals. Appellants contend that "[Florida's] state law obligations require Baptist to maintain all state-mandated information separately from any privileged database, so it is accessible to patients and state agencies." Initial Brief of Appellants, p. 28. Having failed to convince the First District that the occurrence reports were not privileged patient safety work product, Appellants flip their argument and contend that state law, rather than the PSQIA, dictates whether documents qualify for federal protection.

Statutory language must be given its plain and ordinary meaning. *Krause v. Textron Fin. Corp.*, 59 So.3d 1085, 1089 (Fla. 2011). Pertinent to this appeal, in order to qualify as privileged patient safety work product, reports must be created or assembled to send to a patient safety organization and have the potential to improve patient safety in order to attain federal protection. 42 U.S.C. § 299b-21(7)(A). Beyond that, information which is "collected, maintained, or developed separately, or exists separately, from a patient safety evaluation system" is not patient safety work product. 42 U.S.C. § 299b-21(7)(B)(ii) (emphasis supplied). Here, Baptist offered unrefuted evidence that the subject occurrence reports were maintained within its patient safety evaluation system.

Without citation to any statutory authority, Appellants contend that the Florida statutory scheme requires that the subject occurrence reports be maintained separately from Baptist's PSES. Nowhere in the Florida statute is such a

requirement expressed. The pertinent statute, at best, grants state regulators, not state court litigants, "access" to the occurrence reports. § 395.0197 (13), Fla. Stat. (2014). The implementing regulation mandates that incident reports "shall be made available for review to any authorized representative of the Agency upon request during normal working hours." Fla. Admin. Code R. 59A 10.0055(3)(b). Providers who fail to provide regulators with access may face heavy penalties. Nowhere does the statute provide litigants with access to the documents.

Nothing within the PSQIA should be construed to "limit" the "reporting" or "recordkeeping" requirements imposed under federal, state or local law. 42 U.S.C. §§ 299b-21(7)(B)(iii)(II-III). Thus, the critical inquiry is the meaning of "reporting" and "recordkeeping" under the PSQIA.

"Reporting" as used in Section 299b-21(7)(B)(iii)(II), must be defined according to its ordinary meaning. The plain meaning of the verb "report" means "to make known to the proper authorities" such as to "report a fire." Report Definition, Merriam-Webster.com, https://www.merriam-webster.com/dictionary/report (last visited April 22, 2016). The word connotes an affirmative act in which information from one party is conveyed to another. In fact, the context in which "reporting" is used in the PSQIA's CLARIFICATION only confirms that it requires an affirmative conveyance. *See* 42 U.S.C. § 299b-21(7)(B)(ii)(II) ("the reporting of information described in this subparagraph **to** a Federal, State, or local

governmental agency …") (emphasis added).

By contrast, §§ 395.0197(1)(e) & (4) Fla. Stat. (2014), requiring the creation of internal incident reports related to statutorily defined "adverse incidents," contains no requirement that these records be reported to any outside agency; only that the state be permitted "access." *See* §§ 395.0197(1)(e), (4), & (13), Fla. Stat. (2014); Fla. Admin. Code R. 59A-10.0055(3)(b). Where a statute employs one word in one place and different word in another, the presumption is that the different terms have different meanings. *Cannon v. Univ. Chicago*, 441 U.S. 677, 696-98 (1979). When the Florida legislature enacted Section 395.0197, it used the word "submit" or "report" when it required providers to convey or transfer information to the regulatory agency. *See* §§ 395.0197(6) & (7), Fla. Stat. (2014). It did not do so with regard to incident reports. *See id*. at (13). "Access" means "the freedom or ability to obtain or make use of something." Access Definition, Merriam-Webster.com, https://www.merriam-webster.com/dictionary/access(last visited April 22, 2016). It requires no affirmative conveyance and merely creates a possible, future review or acquisition of information. This Court has interpreted Amendment 7 consistently with the ordinary meaning of "access," finding that the purpose of the amendment is "to give patients, **upon request**, the right to review records of health care facilities or providers adverse medical incidents, including those which could

cause injury or death." *West Florida Reg. Med. Ctr. Inc. v. See*, 79 So. 3d at 1 (Fla. 2012) (emphasis supplied and citations omitted). Read as a whole, nothing within the statutory definition of "patient safety work product" prohibits the collection and maintenance of records within a PSES which are required to be created under state law so long as the provider is not obligated to "report" those records to a state agency. "Report" does not mean "access." Therefore, the ordinary meaning of "reporting" as used by Congress in the CLARIFICATION does not encompass the granting of "access" to a document as described in the pertinent Florida statutes and constitutional provision.

Moreover, nothing in the PSQIA prohibits the privilege from having some effect upon state recordkeeping obligations so long as those obligations are not "limited." 42 U.S.C. § 299b-21(7)(B)(iii)(III). Baptist's collection and maintenance of statutory "adverse incident" records within its PSES also does nothing to limit a state "recordkeeping" requirement. "Recordkeeping" means "the act or process of creating and maintaining records." Recordkeeping Definition, The Collins English Dictionary Online, http://www.collinsdictionary.com/Dictionary/English/recordkeeping (last visited April 22, 2016). "Limit" is defined as "to curtail or reduce in quantity or extent." Limit Definition, Merriam-Webster.com, https://www.merriam-webster.com/dictionary/limit (last visited April 22, 2016). Florida hospitals, including Appellee, are required to maintain,

but not report, certain records under §§ 395.0197(1)(e) & (4), Fla. Stat. (2014), including records which might constitute "adverse incident" records under Amendment 7. Such records must still be created and maintained under Florida law, although such records are privileged under the PSQIA. Thus, the privilege imposes no limitation on the provider's obligation to keep state-mandated records.

In order to encourage widespread provider participation in the PSQIA, the United States Department of Health and Human Services chose to make participation as administratively easy and cost-efficient as possible. 73 Fed. Reg. 70732, 70741 (November 21, 2008). Recognizing that requiring providers to maintain duplicative information systems would discourage participation, HHS, through its duly-promulgated regulations, permits providers to remove patient safety work product from its patient safety evaluation system so long as the information has not yet been transmitted to a PSO and the provider documents its action. 42 C.F.R. § 3.20 Definition of Patient Safety Work Product (2)(ii)(A)-(B).

This provision dovetails with Florida's regulatory scheme requiring the creation of internal risk management programs. Florida regulators obtain access to the occurrence reports "upon request." Fla. Admin. Code R. 59A-10-0055(3)(b). The PSQIA guarantees access by oversight entities to "the original information in the same manner as such entities have had access prior to the passage of the Patient Safety Act." 73 Fed. Reg. at 70742. As in the past, Florida regulators can

continue to request access to the occurrence reports. HHS is clear that external regulatory obligations must be satisfied with non-privileged information. If the report has not been transmitted to a PSO, it may be provided to the regulator. If it has been transmitted to a PSO, the report may not be provided to the state regulator. But state regulators are in no worse position than they were before passage of the PSQIA when providers were free to acquiesce to the request, provide original documents to assist regulators in their investigation, or refuse to cooperate and face sanctions. The fact that regulators may eventually obtain access to the occurrence reports while litigants may not simply due to fortuitous timing is not a reason to deny the privilege protections under the Act. Nothing in the PSQIA requires that regulators and litigants have either equal access or access to information simultaneously.

Accordingly, the occurrence reports are plainly patient safety work product under the PSQIA.

III. Patient Safety Work Product Can Be Used Internally For Any Purpose Including Any Requirement To Maintain Incident Reports Within Its Internal Risk Management Program

Appellants mistakenly persist in their dual purpose argument, contending that the creation or assembly of the information must be for the sole purpose of transmitting it to the PSO. First, nowhere in the definition of patient safety work product does the word "sole" or any of its synonyms appear. *See* 42 U.S.C. §

299b-21(7). Second, the Act expressly provides that none of its provisions prohibit "any person from conducting additional analysis [of patient safety work product] for *any purpose*" even if that analysis involves issues similar or identical considered by the PSO or within the PSES. 42 U.S.C. § 299b-22(h). Third, patient safety work product can be used internally within an organization for "any purpose." 73 Fed. Reg. at 70779; *see also id.* at 70737. ("The final rule does not limit the purpose for which patient safety work product may be shared internal to an entity.") These internal uses include, but are not limited to, "educational, academic or other professional purposes" (*id.* at 70778), or "credentialing, disciplinary or peer review purposes." (*id*. at 70779).

Florida law mandates the creation of an "internal" risk management program. §395.0197(1), Fla. Stat. (2014) Providers need only "file" incident reports with their own risk managers. *Id*. at (4). As providers can use patient safety work product internally for "any purpose" under the federal act, the use of patient safety work product occurrence reports as part of a state-mandated internal risk management program is consistent with both the PSQIA and state law.

In order to be privileged, the information or reports need only be created or assembled to disclose to a PSO. The fact that such reports are used for other purposes is expressly permitted by the Patient Safety Act and does not vitiate the privilege. Appellants' dual purpose argument is therefore simply incorrect.

CONCLUSION

This Court must interpret the PSQIA to the fullest extent of the language of the Act's privilege protections in order to achieve Congress' purpose to create an environment in which providers, assisted by PSOs, can collect data and perform self-critical analysis necessary to improve patient safety and save lives. The PSQIA and its associated regulations permit providers to maintain information within their patient safety evaluation systems while still satisfying state-mandated recordkeeping requirements. The Appellee's occurrence reports constitute patient safety work product and are privileged.

Date: May 2, 2016

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CERTIFICATE OF SERVICE

I HEREBY CERTIFY that a true and correct copy of the foregoing has been electronically filed using the Supreme Court of Florida's e-Portal system, and I further certify it has been furnished to the individuals identified on the attached Service List via electronic mail on May 2, 2016.

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CERTIFICATE OF COMPLIANCE WITH FONT REQUIREMENT

I certify that the foregoing Amicus Brief is prepared in 14-point Times New Roman Font and complies with the font requirements of Florida Rule of Appellate Procedure 9.210(a)(2).

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