

Comments of the Independent Regulatory Review Commission



Department of Human Services Regulation #14-546 (IRRC #3209)

Intensive Behavioral Health Services

October 4, 2018

We submit for your consideration the following comments on the proposed rulemaking published in the August 4, 2018 *Pennsylvania Bulletin*. Our comments are based on criteria in Section 5.2 of the Regulatory Review Act (RRA) (71 P.S. § 745.5b). Section 5.1(a) of the RRA (71 P.S. § 745.5a(a)) directs the Department of Human Services (Department) to respond to all comments received from us or any other source.

- 1. Determining whether the regulation is in the public interest; Economic or fiscal impacts; Direct and indirect costs to the Commonwealth, to its political subdivisions and to the private sector; Adverse effects on prices of goods and services, productivity or competition; Protection of the public health, safety and welfare; Need for the regulation; Reasonableness of requirements, implementation procedures and timetables for compliance.**

According to the Department, the purpose of this rulemaking is to codify minimum licensing standards and program requirements for participation in the Medical Assistance (MA) Program and MA payment for conditions for agencies that deliver intensive behavioral health services (IBHS) to children, youth and young adults with mental, emotional and behavioral health needs. The rulemaking will replace the requirements for behavioral health rehabilitation services (BHRS) set forth in bulletins issued by the Department. Sections of the rulemaking that address applied behavioral analysis (ABA) services are required by a settlement reached in *Sonny O. v. Dallas*, No. 1:14-CV-1110 (M.D. Pa 2016) (*Sonny O.*).

In developing this regulatory package, the Department convened a workgroup consisting of approximately 75 individuals representing an array of stakeholders to provide input. The workgroup held a total of 12 meetings and received additional opportunities to submit written comments. We acknowledge the amount of time and effort that the Department has put into this regulatory package thus far.

Comments on the proposed rulemaking have been submitted by two legislators, parents, providers of BHRS and IBHS, associations, attorneys, licensed mental health professionals and counties. As evidenced by the number and scope of comments received on this proposal, numerous concerns remain. Although the commentators have raised many concerns from various perspectives which will be discussed below, they agree with the intended goal of the

rulemaking – improved access and care for children, youth and young adults with mental, emotional and behavioral health needs. To that end, we note that Section 2 of the RRA, pertaining to legislative intent, provides the following direction: “To the greatest extent possible, this act is intended to encourage the resolution of objections to a regulation and the reaching of a consensus among the commission, the standing committees, interested parties and the agency.” 71 P.S. §745.2(a). In order to resolve concerns raised by commentators and achieve the goals of this proposal, we encourage the Department to continue to meet with the regulated community on this rulemaking to reach a consensus.

The following comments address general concerns related to the rulemaking as a whole and also recurring issues throughout the rulemaking. Beginning with Comment #2, we address more specific issues pertaining to various sections of the regulation.

Need for the regulation; Reasonableness of requirements

The Preamble and Regulatory Analysis Form (RAF) explain that this rulemaking will replace BHRS bulletins used by the Department. It is unclear from the description of the rulemaking provided in the Preamble if any of the language from those bulletins was carried over to the rulemaking. In addition, while the Preamble provides a description of the regulatory language in Annex A, it does not explain the need for it. In order for this Commission to determine the need for the regulation and the reasonableness of the requirements, we ask the Department to provide an explanation of the rationale for each section and to explain if that language previously existed in bulletins issued by the Department. Also, we ask the Department to identify language in the ABA sections of the rulemaking that satisfy requirements of the settlement agreement reached in *Sonny O.*

Protection of the public health, safety and welfare

Senator Mike Regan and Representative Greg Rothman submitted a joint comment letter on the proposed rulemaking. They are concerned the regulation will be harmful to those in need of ABA therapy because it will reduce access to qualified providers while lowering standards. Specifically, they state, “It is imperative that individuals with disabilities have highly trained, capable persons treating them. Lowering the standard supervisor requirement to only require a bachelor’s degree, four classes in ABA, six months of experience, and two hours a month of supervision by a [board-certified behavior analyst (BCBA)], will have a severe negative impact on those that it is aimed to help.” Many parents that submitted comments also identified these issues as significant areas of concern.

We agree that children, youth and young adults in need of mental, emotional and behavioral health services deserve to be treated by highly trained and capable professionals. We ask the Department to explain how the supervisory standards included in the final rulemaking ensure the protection of children, youth and young adults receiving services.

Direct and indirect costs to the Commonwealth, to its political subdivisions and to the private sector

We have two concerns with the rulemaking pertaining to direct and indirect costs. The first relates to costs to the regulated community. Section 19 of the RAF indicates that there will be increased costs associated with the rulemaking for the regulated community, but the Department believes many of those costs will be offset by corresponding savings. The regulated community, particularly behavioral health agencies, disagree with this analysis. They believe there are many new mandates, such as additional training and certifications in Sections 5240.71 (relating to staff qualifications) and 5240.73 (relating to staff training requirements) that will not be offset by corresponding savings. We ask the Department to work with the regulated community to gain a better understanding of the fiscal impact the regulation will have on these agencies and to provide a more detailed fiscal analysis of those findings in the RAF submitted with the final regulatory package.

Our second concern relates to the potential impact the rulemaking could have on state government. The RAF submitted with the rulemaking indicates that there will be no costs to state government. Some commentators believe costs to state government will increase because of new mandates such as those found in Section 5240.61 (relating to quality improvement requirements). Commentators assert that providers will seek additional reimbursement from the state because of the added duties and requirements imposed by the regulation. We ask the Department to explain how the final regulation will impact reimbursement rates to be paid by state government and to quantify those costs.

Adverse effects on prices of goods and services, productivity or competition

We have concerns that an unintended consequence of this rulemaking could be less access to behavioral health services for children, youth and young adults. Both parents and providers have expressed concern that the rulemaking, as written, will make it more difficult to find and retain qualified staff. While this is clearly not the intent of the Department, there is confusion in the regulated community about the effects that the rulemaking will have. Another unintended adverse effect of the rulemaking, as expressed by commentators, is that the mandates of the regulation will force providers to use fewer independent contractors and hire more employees. As an example, a commentator stated, "If the proposed regulations are approved, many agencies may be forced to convert from the independent contractor structure currently utilized to employee status, resulting in increased costs and administrative responsibilities that may jeopardize the financial stability of IBHS programs." We ask the Department to explain how the final rulemaking will ensure the availability of qualified staff rather than cause the adverse effects asserted by the regulated community.

Reasonableness of requirements, implementation procedures and timetables for compliance

In the Preamble, the Department explains that IBHS agencies that hold an outpatient psychiatric clinic, a psychiatric partial hospitalization program or family based mental health license and currently provide IBHS will be required to comply with the final-form rulemaking as of its effective date, and will be required to obtain a license under Chapter 5240 upon expiration of

their current license. The Department states that IBHS agencies that are approved to provide ABA services as of the effective date of adoption of this rulemaking will be required to comply with the final-form regulation as of its effective date, and will be required to obtain a license under Chapter 5240 within 180 days of the effective date of Chapter 5240. We have three questions relating to the effective date. First, why are the timeframes to obtain a license under Chapter 5240 different for IBHS agencies depending on whether ABA services are provided? Second, assuming this regulatory package is ultimately published as a final rulemaking in the *Pennsylvania Bulletin*, how long after that will the rulemaking become effective? Third, what training plans does the Department have to ensure IBHS agencies are equipped to implement the new regulations? Given the number of new requirements, as well as the additional certifications and training that the rulemaking requires, we urge the Department to consult with the regulated community to determine how much time is needed to make the transition from the current regulatory environment to the new one. The Department should also address the above questions in the Preamble or separate comment and response document that accompanies the final-form regulation.

CHAPTER 1155. INTENSIVE BEHAVIORAL HEALTH SERVICES

GENERAL PROVISIONS

2. Section 1155.2. Definitions. – Clarity and lack of ambiguity.

EBT–Evidence-based therapy

We have two concerns with this definition. First, under Subparagraph (i), a commentator has stated that the National Registry of Evidence-based Programs and Practices has been phased out and replaced with the Evidence-Based Practices Resource Center. We ask the Department to ensure this definition is citing the appropriate practice. Second, under Subparagraph (v), the Department should clarify how a therapy would become designated as a “model intervention.” The process and criteria the Department uses should be included in the body of the regulation. This language also appears in Section 1155.34 (relating to payment conditions for EBT) and Section 5240.2 (relating to definitions).

SCOPE OF BENEFITS

3. Section 1155.11. Scope of benefits. – Clarity and lack of ambiguity.

This section states the following: “Children, youth or young adults under 21 years of age with behavioral health diagnoses are eligible for the full range of covered IBHS.” What is meant by the term “behavioral health diagnoses”? We ask the Department to define this term. Also, since a young adult is defined as a person who is “under 21 years of age,” the Department should delete the phrase *under 21 years of age* from all subsequent references to young adults. This also applies to Section 5240.1 (relating to scope).

PROVIDER PARTICIPATION

4. Section 1155.22. Ongoing responsibilities of providers. – Clarity and lack of ambiguity.

This section addresses ongoing responsibilities of IBHS agencies. We have three concerns. First, Subsection (c) requires an IBHS agency to have a current license for each branch or satellite location. We ask the Department to clarify the basis for requiring each branch and satellite location to have a separate license. Second, Subsection (d) requires each branch or satellite location of a licensed IBHS agency to be *enrolled* by the Department. (Emphasis added.) What is the difference between being licensed and enrolled? This should be clarified in the final-form regulation. Third, Subsection (e) requires an IBHS agency to notify the Department of a change in name, address or services provided. Will any of these changes require Department approval, particularly if they differ from what was listed in the license or enrollment application? If so, that should be specified in the final-form regulation.

PAYMENT FOR INTENSIVE BEHAVIORAL HEALTH SERVICES

5. Section 1155.32. Payment conditions for individual services. – Economic or fiscal impacts; Clarity and lack of ambiguity; Reasonableness of requirements; Implementation procedures.

This section, as well as Section 1155.36(1) (relating to covered services), restricts payment to “individual services.” A commentator asserts that behavior specialists and other treatment professionals should be paid when they consult with parents, teachers and other caregivers. We ask the Department to address the reasonableness of not including consultations as a condition of payment in this and other sections of Chapter 1155 relating to payment conditions.

Commentators seek clarification on terms of payment when an assessment or individual treatment plan (ITP) is not completed within indicated timeframes. How will this provision be implemented? This comment applies to each of the sections in Chapter 1155 relating to payment conditions.

The term “initiation,” which is found for the first time in Subparagraph 1(i) and used throughout the regulation, raises concerns for commentators related to the meaning of “initiation of IBHS” and variations thereof. Specifically, what constitutes the “initiation” of services? Is that date determined by the Department or the provider? Since variations of this phrase are used in both Chapter 1155 and 5240, we ask the Department to define the term in each chapter and use it consistently throughout the regulation.

Commentators raise two concerns related to Subparagraph (1)(ii). The first concern relates to “other licensed professional whose scope of practice includes the diagnosis and treatment of behavioral health disorders.” What other licensed professionals, besides those listed, qualify to diagnose and treat behavioral health disorders? Commentators are concerned that this other

option could lead to a loss of clinical expertise, or in the alternative, could require additional oversight and review to ensure quality of work. We note this language is also found in Section 1155.33(1)(ii) (relating to payment conditions for ABA). The second concern relates to the requirement that a written order for services must include a behavioral health disorder diagnosis. The language “behavioral health disorders” could be read narrowly to exclude, for example, Intellectual Disability, a condition for which ABA might be medically necessary. We ask the Department to clarify the final form regulation related to both points.

Under Subparagraph (2)(vii), we ask the Department to clarify who would qualify as an “other professional” since this person has the authority to determine that an updated assessment is needed. This comment also applies to Sections 5240.85(e)(7) (relating to assessment) and 5240.86(f)(7) (relating to individual treatment plan).

Similar to our comment above related to the term “initiation,” we ask the Department to define the term “reinitiation,” which is found in Paragraph (7), as well as in each of the remaining sections of Chapter 1155 relating to payment conditions. Commentators raise concerns about the implementation of this concept. Is this an exemption from going through the initial procedures? Are there any limits on the number of times an individual can reinitiate services? We ask the Department to clarify this term here and in Chapter 5240.

6. Section 1155.33. Payment conditions for ABA. – Clarity and lack of ambiguity; Reasonableness of requirements.

Commentators note that Paragraph (2) does not include a timeframe for conducting the face-to-face assessment like the sections for payment conditions for individual services, EBT and group services. We ask the Department to explain why this section is not consistent with the others.

7. Section 1155.34. Payment conditions for EBT. – Clarity and lack of ambiguity; Implementation procedures.

As a condition of payment, Paragraph (7) requires an IBHS agency to have a current certification or licensure from the national certification organization or entity that developed or owns the EBT provided. A commentator raises concerns that this differs from the standard found in Section 5240.93(a) (relating to EBT requirements) that specifies a certification or license is only necessary if it is “required to provide the EBT.” The commentator expresses concern that some EBTs do not have a national certification process. We ask the Department to clarify and explain how this requirement will be implemented.

8. Section 1155.35. Payment conditions for group services. – Clarity and lack of ambiguity.

In Paragraph (2) and elsewhere in the regulation, the Department uses the phrase “mental health professional.” We ask the Department to define this term in both Chapters 1155 and 5240.

CHAPTER 5240. INTENSIVE BEHAVIORAL HEALTH SERVICES

GENERAL PROVISIONS

9. Section 5240.2. Definitions. – Protection of the public health, safety and welfare; Clarity and lack of ambiguity.

We have several comments about the acronyms used within the regulation. In general, we have a concern about the number of acronyms, which a parent described as “overwhelming.” Also, many job titles are used throughout the regulation which are not defined, such as behavior specialist analyst, behavior specialist, mobile therapist, behavior health technician, mental health professional and mental health worker. And while the Department identifies many positions/professions, not all are defined so as to differentiate between them. For example, how does a behavioral health technician (BHT) differ from a behavioral health technician-applied behavioral analysis (BHT-ABA)? We ask the Department to define each position/profession and make clear how each differs from the others. Additionally, we note that qualifications for licensure as a behavior specialist are found under 49 Pa. Code Section 18.524 (relating to criteria for licensure as behavior specialist) and ask the Department to include that reference in the definition.

Also, based on commentator concerns, we ask the Department to define the terms “provider” and “skill deficits,” as well as the term “community” for ABA purposes.

ASD –Autism spectrum disorder

We note that the proposed definition of this term differs from the definition found in 49 PA Code Section 18.522 (relating to definitions). We ask the Department to explain why this definition differs from the State Board of Medicine regulations that license behavior specialists.

BHT–Behavioral health technician

Commentators assert that there is no current certification for BHT in Pennsylvania., and the Department acknowledges in the Preamble that it will be engaging the Pennsylvania Certification Board (Board) to develop state-specific certifications as required by the regulation. We note that Sections 5240.73 (relating to staff training requirements) and 5240.81 (relating to staff qualifications) each rely on the Board for certifications required by the regulation. Commentators suggest reliance on an existing certification board as an alternative. We ask the Department to explain the process whereby it will engage the Board to ensure that those certified by the Board meet the Department’s standards for training and competency.

Group services

The last sentence of this definition states, “When included in a child’s, youth’s or young adult’s ITP, group services may include individual interventions.” This sentence is substantive and should be moved to the body of the regulation.

Stimulus

This term is defined as, “An event, circumstance or condition that can be changed or does change based upon the behavior specialist analyst’s manipulation.” We ask the Department to explain why this definition is specific only to a behavior specialist analyst.

10. Section 5240.5. Service description. – Reasonableness of requirements, implementation procedures and timetables for compliance.

Subsection (a) states, “As part of the initial licensing application, the IBHS agency shall submit to the Department for review and approval a written description of services to be provided” We ask the Department to explain the process for reviewing and approving the written description of services.

Subsection (b) requires an IBHS agency to notify the Department prior to changing its services or if the information in the service description is no longer accurate. Since any change requires Department approval, we ask the Department to explain how this approval process works, what timeframes are involved, and how the Department will notify the IBHS agency of its decision. Also, we ask the Department to include this process in the final regulation.

11. Section 5240.6. Restrictive procedures. – Protection of public health, safety and welfare; Clarity and lack of ambiguity; Reasonableness of requirements.

This sections includes specific requirements related to the use of restrictive procedures. Commentators have expressed concerns with this section. First, in Subsections (e) and (f)(3), it has been suggested that the phrase “regain self-control” be replaced with “no longer an imminent danger to self or others” as this is a best practices guideline. Second, a commentator asks the Department to ensure that the final regulations are consistent with the Pennsylvania Department of Education regulations to reduce conflict for the BHT and BHT-ABA who deliver services in schools. We agree that these suggestions improve the clarity and assist with the implementation of the rulemaking. We ask the Department to revise these provisions.

Under Subsection (h), it is unclear how long an IBHS agency must keep a record of each person’s training in the use of manual restraint procedures. We ask the Department to clarify this requirement. Also, we ask the Department to include a cross-reference to recordkeeping requirements in Section 5240.42 (relating to agency records).

12. Section 5240.7. Coordination of services. – Clarity and lack of ambiguity.

Under Subsection (c)(3), an IBHS agency must make available information on community behavioral health resources, including the address and phone number of the program or organization. We ask the Department to expand this information to include a website, if available.

Subsection (f) states, “An IBHS agency that provides group services is not required to comply with subsections (a) and (b).” We ask the Department to explain the reasonableness of exempting IBHS agencies that provide group services from these subsections relating to written agreements. A commentator states that all IBHS agencies should have these and update them routinely.

STAFFING

13. Section 5240.11. Staff requirements. – Economic or fiscal impacts; Clarity and lack of ambiguity; Need for the regulation; Reasonableness of requirements.

This section specifies the responsibilities of an IBHS agency’s administrative director and clinical director. Commentators question the need and rationale for the detailed description of these responsibilities. For example, what is the rationale for mandating by regulation that an administrative director dedicates a minimum of 7.5 hours each week for each IBHS agency the director oversees? What is the need and rationale for mandating and documenting monthly meetings between the clinical director and staff? What is the need for this level of oversight by an administrative director? We ask the Department to explain the need for and reasonableness of staff requirements in this section.

Also, commentators raise concerns that the language in this section does not recognize the use of independent contractors and consultants. We ask the Department to clarify whether the requirements listed apply to contractors/consultants, and if they do, we ask the Department to amend the regulation accordingly. If the requirements do not apply to contractors/consultants, the Department should explain why they do not apply. This concern applies to each of the staffing sections, including Sections 5240.12 (relating to staff qualifications), 5240.13 (relating to staff training plan), 5240.71 (relating to staff qualifications), 5240.72 (relating to supervision), 5240.73 (relating to staff training requirements), 5240.81 (relating to staff qualifications), 5240.82 (relating to supervision) and 5240.101 (relating to staff requirements and qualifications).

14. Section 5240.12. Staff qualifications. – Economic or fiscal impacts; Clarity and lack of ambiguity; Need for the regulation; Reasonableness of requirements.

Subsection (a) establishes the qualifications of an administrative director of an IBHS agency. Commentators question the rationale for requiring an administrative director to have a graduate degree, and ask if a bachelor’s degree plus experience would be an acceptable alternative. We ask the Department to explain the need for and reasonableness of this requirement. This comment also applies to Section 5240.81 (relating to staff qualifications).

Paragraph (b)(1) provides a “minimum of 1 year of full-time postgraduate experience in the provision of mental health direct service to children, youth or young adults” as one of the criteria a clinical director of an IBHS agency must meet. We ask the Department to clarify what

constitutes “experience” in the provision of mental health direct service to children, youth or young adults. A commentator states that working with children in a school, daycare or other Child and Adolescent Service System Program qualified previously toward experience. This comment applies to other similarly worded provisions including. Sections 5240.71 (relating to staff qualifications), 5240.72 (relating to supervision), and 5240.81 (relating to staff qualifications).

15. Section 5240.13. Staff training plan. – Economic or fiscal impacts; Clarity and lack of ambiguity; Need for the regulation; Reasonableness of requirements.

Commentators assert that the requirement of Subsection (a)(1)(i) to update training plans annually for each individual based on date of hire and the requirement of Subsection (e)(6) to keep a copy of written material distributed to individuals is burdensome, costly and does not provide a benefit. A commentator suggests removing “date of hire” language to ease some of the burden. We ask the Department to explain the need for and reasonableness of the requirements in these subsections.

Subsection (e)(7) requires an IBHS agency to keep records regarding Department approval of training. We ask the Department to explain the process for obtaining approval of training, what time frames are involved, and how the Department will notify the IBHS agency of its decision. This comment also applies to Section 5240.73 (relating to staff training requirements). The process for obtaining approval of training should be set forth in the regulation.

SERVICE PLANNING AND DELIVERY

16. Section 5240.21. Assessment. – Economic or fiscal impacts; Protection of public health, safety and welfare; Clarity and lack of ambiguity; Need for the regulation; Reasonableness of requirements.

Commentators raise several concerns and questions related to Subsection (a). First, a comprehensive face-to-face-assessment must be completed by a behavior specialist or a mobile therapist within 15 days of the initiation of IBHS and prior to developing the ITP. As noted in Comment #5, commentators ask for clarification as to when services are “initiated.” Second, commentators assert that the 15-day time limit is too short in light of challenges with scheduling families. Third, commentators assert that it is inappropriate for this assessment, and the six-month assessment in Subsection (e), to be completed by a person without a professional license. Commentators ask that the assessment be done by a licensed professional or under the supervision of a licensed professional. Finally, a commentator questions whether the face-to-face assessment would be done in place of a psychological evaluation, or if both are required. We ask the Department to explain the need for and reasonableness of the timeframe for the assessment, and to explain how the health, safety and welfare of children, youth and young adults will be protected by the level of expertise and experience of the person assessing them. Additionally, we ask the Department to clarify in the final regulation requirements related to face-to-face assessments and psychological evaluations.

17. Section 5240.22. Individual treatment plan. – Clarity and lack of ambiguity; Reasonableness of requirements, implementation procedures and timetables for compliance.

This section addresses requirements of an ITP administered by an IBHS agency. We have three concerns. First, a commentator asks for clarification as to who is responsible for the development of the ITP. We ask the Department to clarify who is responsible for developing the ITP.

Second, Subsection (c) states that the ITP shall be “strength-based.” What does this mean? We ask that this term be clarified in the final-form regulation. This language also appears in Sections 5240.86 (relating to individual treatment plan) and 5240.106 (relating to individual treatment plan).

Third, Subsection (d)(3) identifies a “safety plan to prevent a crisis, a crisis intervention plan and a transition plan.” What is meant by the term “crisis”? What is a “crisis intervention plan” and a “transition plan”? We note that the term “crisis event” is used in Chapter 1155. We ask the Department to clarify these terms, as well as the intent of a transition plan.

18. Section 5240.23. Service provision. – Clarity and lack of ambiguity; Reasonableness of requirements, implementation procedures and timetables for compliance.

Subsection (b) states that IBHS shall be delivered in community-based, clinically appropriate settings. A commentator asks for clarification as to what is meant by “community-based.” We ask the Department to clarify whether this includes a home, a school or other location.

DISCHARGE

19. Section 5240.31. Discharge. – Clarity and lack of ambiguity; Reasonableness of requirements, implementation procedures and timetables for compliance.

As noted in Comment #5, commentators have concerns related to reinitiation under Subsection (c). They ask if a new written order will be required and if there will be additional paperwork associated with the reinitiation. A commentator points out that it may be difficult to assign the patient to the same caregiving team, and asks that the regulation provide for reassessment to ensure the need for reinitiation is valid, as well as to update the treatment plans and goals. We ask the Department to clarify the requirements and intentions related to reinitiation in the final-form regulation.

20. Section 5240.32. Discharge summary. – Reasonableness of requirements, implementation procedures and timetables for compliance; Economic or fiscal impact.

Subsection (a)(4) requires an IBHS agency to document at least two telephone contacts within the first 30 days after discharge to monitor the status of maintaining treatment progress. Commentators suggest the requirement should be changed to attempted contacts, and recommend other modes of communication such as secure emails be permissible. We ask the Department to consider these suggestions, and if the health, safety and welfare of children, youth and young adults would be adequately protected, to adopt the recommendations in order to lessen the fiscal impact of the rulemaking.

RECORDS

21. Section 5240.41. Individual records. – Need for the regulation; Reasonableness of requirements.

A commentator asserts that the requirement under Subsection (b)(3) to review records for quality at least every six months is excessive. Another commentator asks if all records must be reviewed or if a sample would be acceptable because reviewing all records is simply not feasible for a large agency. We ask the Department to explain the need for and the reasonableness of a quality review of all records at least every six months.

22. Section 5240.42. Agency records. – Need for the regulation; Reasonableness of requirements.

This sections identifies the different records that must be kept by an IBHS agency. We have three questions. First, how long must the records be kept? Second, can they be kept in electronic format? Third, what is the need for keeping records such as staff work schedules, daily schedules for group services? We ask the Department to explain the need for and reasonableness of the record-keeping requirements in the final regulation.

QUALITY IMPROVEMENT

23. Section 5240.61. Quality improvement requirements. – Economic or fiscal impacts; Clarity and lack of ambiguity.

This section establishes the requirements for quality improvement plans of an IBHS agency. We have two concerns. First, under Subsection (a), what is a “quality improvement plan”? We ask the Department to define this term.

Second, Subsection (c) requires an IBHS agency to make annual quality reports available to the public. We have two concerns. First, a commentator asks the Department to clarify the information that needs to be shared with the public related to annual quality reports. We ask the

Department to work with the regulated community to ensure the final-form regulation is clear on what is to be published. Second, since this information would be useful to those in need of IBHS services, the Department should require these reports to be posted on each IBHS agency's website and included in advertising literature.

INDIVIDUAL SERVICES

24. Section 5240.71. Staff qualifications. – Economic or fiscal impacts; Protection of public health, safety and welfare; Clarity and lack of ambiguity.

As noted in Comment #1, we reiterate concerns raised by commentators related to increased costs for staff training and certifications in this section and in Sections 5240.81 (relating to staff qualifications) and 5240.101 (relating to staff requirements and qualifications).

Several commentators express concern that language in Subsection (b) states that a behavior specialist who provides treatment to children diagnosed with ASD shall meet the qualifications for a behavior specialist analyst under Section 5240.81(c) (relating to staff qualifications) under ABA. Does this language limit the treatment approaches available to children with ASD to ABA? Commentators assert that families should have the option of choosing individual services. We ask the Department to clarify the treatment services available to children diagnosed with ASD.

25. Section 5240.72. Supervision. – Economic or fiscal impacts; Clarity and lack of ambiguity; Need for the regulation; Reasonableness of requirements.

This section establishes supervision requirements for IBHS agencies that provide individual services. We have four concerns. First, in general, commentators express concern regarding the "excessive" amount of supervision in this section, particularly as it relates to face-to-face sessions in Subparagraph (a)(2) and direct observation in Subparagraph (a)(3). Commentators note that current supervision standards allow for group supervision, and that the monthly face-to-face sessions for each IBHS staff person will require significant additional time and resources and are not cost-effective. In light of the fiscal concerns previously mentioned, we ask the Department to explain the need for and reasonableness of the level of supervision required in this section.

Second, we also have specific questions related to Subsection (a). What is an "IBHS supervisor"? Would behavior specialists and mobile therapists be included in the supervision requirements under Subparagraphs (a)(2)-(4)? What are the differences between supervision, face-to-face sessions and direct observations? We ask the Department to clarify these provisions in the final regulation.

Third, since Subsection (c) specifies the qualifications for an "IBHS supervisor," we ask the Department to move this language to Section 5240.71 (relating to staff qualifications).

Fourth, Subsection (d) specifies that an IBHS supervisor may supervise a maximum of nine full-time equivalent BHT staff. What is the basis for setting the maximum number at nine, and do IBHS supervisors oversee other types of staff? If so, how many? Commentators assert that the number nine is too restrictive and will require the hiring of additional supervisors. We ask the Department to explain the reasonableness of the limit on the number of staff that can be supervised, and include an explanation for why the number of other staff that can be supervised is not specified.

26. Section 5240.73. Staff training requirements. – Economic or fiscal impacts; Need for the regulation; Reasonableness of requirements.

As noted in Comment #1, commentators assert that training requirements are greatly increased from current requirements which will have a significant financial impact on providers as they are not reimbursed for training. We ask the Department to address the economic impact on the regulated community of increased training requirements in the final regulation.

27. 5240.75. Individual services provision. – Protection of public health, safety and welfare; Reasonableness of requirements.

Subparagraph (a)(5) states that a behavior specialist shall provide a consultation to mobile therapists or BHTs on behavioral management protocols. A commentator states that the consultation should be expanded to include all necessary treatment team members. We ask the Department to explain the reasonableness of not including all necessary treatment team members and how the final regulation protects the health, safety and welfare of children, youth and young adults.

Subparagraph (c)(9) states that a BHT may provide “referrals to other necessary services and supports.” A commentator states that the expertise needed for referrals is more appropriate for behavior specialists and mobile therapists rather than BHTs. Alternately, another commentator states that BHTs should be required to have adequate systems training and knowledge of the continuum of care in order to make referrals for service. We ask the Department to clarify the level of expertise and training necessary for referrals in order to protect the health, safety and welfare of children, youth and young adults.

APPLIED BEHAVIORAL ANALYSIS

28. Section 5240.81. Staff qualifications. – Protection of public health, safety and welfare; Need for the regulation; Reasonableness of requirements.

Subsection (b)(1) requires a clinical director of an IBHS agency that provides ABA services to be a licensed professional and to have a second license or credential in behavior analysis. A commentator opposes this, saying it would unfairly restrict access to services. We ask the Department to explain the need for and reasonableness of this requirement, as well as how it will protect the health, safety and welfare of children, youth and young adults.

Subparagraphs (b)(2) and (3) requires a clinical director to become board-certified within three years of taking on the position. Commentators have concerns that the intent of the regulations and *Sonny O.* could be thwarted by replacing the clinical director every three years. A commentator suggests that the Department provide additional time before this provision takes effect to allow for individuals to become certified, but insists that by a date certain it is critical that all clinical directors be BCBAs since they direct the clinical aspect of an ABA program. Another commentator notes that in order for a registered behavior technician (RBT) to maintain certification, the RBT must be supervised by a BCBA or a board-certified assistant behavior analyst so it is critical for every agency to have BCBAs on staff. We agree that the role of a clinical director is vital and that an opportunity for lowering the qualification standards should not exist each time a position is vacant. We ask the Department to provide a reasonable amount of time for individuals to become certified, but to set a date certain for all clinical directors to meet the requirements of the final regulation.

29. Section 5240.82. Supervision. – Economic or fiscal impacts; Clarity and lack of ambiguity; Need for the regulation; Reasonableness of requirements.

In addition to comments cited under Section 5240.72 (relating to supervision), commentators note that the level of supervision mandated is unnecessary, costly and restrictive. Commentators add that the regulations are so detailed, such as requirements for signatures of supervisors and staff, that it will cause oversight challenges for the Department. In light of the fiscal concerns previously mentioned, we ask the Department to explain the need for and reasonableness of the level of supervision required in this section.

30. Section 5240.83. Staff training requirements. – Reasonableness of requirements, implementation procedures and timetables for compliance.

This section includes several references to training approved by the Behavior Analyst Certification Board or the Department. We ask the Department to explain the process for evaluating and approving training, and how the regulated community is informed of approved training.

31. Section 5240.85. Assessment. – Clarity and lack of ambiguity.

This section specifies the requirements of IBHS agencies providing ABA services to children, youth and young adults. We have two concerns. First, under Subsection (a), we ask the Department to clarify how soon the face-to-face assessment must occur. Second, under Subsection (f), we ask the Department to clarify whether the assessment must also be signed by the parent or caregiver.

32. Section 5240.87. ABA services provision. – Clarity and lack of ambiguity.

Subsection (a)(1) states that a behavior specialist analyst provides certain services including “assessment of skill deficits and behavioral needs.” A commentator states that the history of coverage of ABA under MA in Pennsylvania has been plagued by disputes over which skills may be addressed through ABA. Therefore, we ask the Department to clarify the meaning of the term “skill deficits” as it relates to ABA services.

Also, a commentator has concerns regarding the language in Subsection (c) limiting the services a BHT-ABA can provide. The Department should explain the rationale for limitations specified in this subsection.

EVIDENCE-BASED THERAPY

33. Section 5240.91. EBT initiation requirements. – Clarity and lack of ambiguity; Reasonableness of requirements, implementation procedures and timetables for compliance.

We ask the Department to clarify whether EBT is to be considered a set of treatments that differ from individual, ABA and group services, or whether EBT represents a set of standards that should apply across all individual, ABA or group modalities of services.

Also, based on commentator concerns, we ask the Department to clarify which licensed professionals are permitted to modify EBTs to account for the needs of children.

34. Section 5240.93. EBT requirements. – Protection of public health, safety and welfare; Clarity and lack of ambiguity.

Commentators note that many of the standards/requirements appear to be transferred to other entities when EBT is used. The Department should clarify what standards providers must adhere to when the regulations are silent on issues such as supervision, minimum qualifications, admissions or discharge criteria.

GROUP SERVICES

35. Section 5240.101. Staff requirements and qualifications. – Economic or fiscal impacts; Need for the regulation; Reasonableness of requirements.

Similar to concerns included in Sections 5240.72 (relating to supervision) and 5240.73 (relating to staff training requirements), we ask the Department to address the economic impact on the regulated community of increased qualifications requirements in the final regulation.

36. Section 5240.102. Supervision. – Economic or fiscal impacts; Need for the regulation; Reasonableness of requirements.

This section establishes supervision requirements for IBHS agencies that provide group services. Under Subparagraph (a)(1), we ask the Department to explain the reasonableness of only clinical directors being permitted to supervise mental health professionals.

37. Section 5240.107. Group services provision. – Clarity and lack of ambiguity.

This section specifies the types of services mental health professionals, mental health workers and BHTs can provide. Is there a maximum number of people that can receive group service at a particular time? If so, this should be specified in the final-form regulation.

38. Section 5240.108. Requirements for group services in school settings. – Clarity and lack of ambiguity.

We ask the Department to clarify for the regulated community whether the services in this section include Community School Based Behavioral Health and other similar services currently occurring in the school setting.

Also, we ask the Department to revise Subparagraph (1)(iii) which uses the non-regulatory term “assurances.”

39. Miscellaneous clarity.

RAF

In response to #29, the Department states the expected delivery date of the final-form regulation is the third quarter of 2018. We ask the Department to update the timeframe.

Section 1155.34. Payment conditions for EBT.

Under Paragraph (4), after the reference to Section 5240.92, the “(relating to . . .)” language is missing. Also, the subparagraphs are numbered incorrectly: (vii) should be (vi) and (viii) should be (vii).

Section 5240.72. Supervision.

Subsection (f) references “audio *and* video transmission.” Subsection (g)(2) references “audio *or* video medium.” (Emphasis added.) The Department should clarify how supervision can be conducted and make it consistent throughout the final-form regulation. Similar language appears in Section 5240.82(h) and (i)(2) and Section 5240.102(d) and (e)(2).