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Independent Regulatory Review Commission

Melmark

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December 2, 2024

Submitted electronically via irrc@irrc.state.pa.us

Re: Proposed regulatory changes to 55 PA. Code Chapter 3800, along with creation of new chapters: 1330 and 5330, designed to codify the minimum licensing standers, Medical Assistance (MA) participation requirements and MA payment conditions for PRTFs that serve children, youth, or young adults with a behavioral health diagnosis.

Dear Colleagues,

Melmark appreciates the opportunity to provide public comments on the Department of Human Services' (DHS) proposed regulatory changes to Psychiatric Residential Treatment Facilities (i.e., IRRC Number 3417). Below, please find our feedback. While we do support the overall goals of making PRTF's safer along with providing family first, trauma informed care, we are extremely concerned the regulations present barriers to serving certain populations that benefit from intensive residential level of care. Specifically, individuals with profound autism spectrum disorder (ASD) and at least moderate intellectual developmental disabilities (IDD) present unique challenges with cognitive abilities, communication impairment, severe aggression and self-harm, and limitations with social interactions. Certain aspects of the proposed regulations are contraindicated for the core presenting symptoms and treatment for these individuals. For example, an individual may have very limited receptive and expressive language, find social situations very aversive, and engage in repetitive and restrictive behaviors that are harmful (e.g., self-injury). Participating in mandated social group therapy, talk-based individual therapy, and delaying supportive protective measures during a crisis (e.g., approval for a physical restraint) are not in the best interest of the individual and long-term progress or best outcomes.

We recognize the need for the state to maintain compliance with federal rules associated with Medicaid match funds and applaud the state for ensuring fidelity. Our general recommendation is that flexibility must be created for compliance with the federal regulations and that state regulations are inclusive of multiple different program models serving multiple different need groups. These regulations must not be one size fits all and should be informed by peer reviewed research that has demonstrated best outcomes for that individual's disability. To best support readers, our comments start with a description of the current Melmark residential treatment

facility (RTF). We believe it is important for regulatory agencies to understand different program models designed to support the various needs of different clinical presentations, and how the proposed regulations might impact them positively and negatively. The program model description is followed by general comments regarding the regulations and the evaluation criteria utilized by the Independent Regulatory Review Commission (IRRC). We then provide comments on the federal portion of the regulations (i.e., Title 42, Chapter IV, Subchapter C, Part 441 Subpart D and Part 483). The comments on federal regulations are solely for context of subsequent comments of the proposed regulations. The federal comments are followed by comments specific to the Pennsylvania regulations (i.e., PA Code Title 55 Chapters 1330, 3800, and 5330).

Melmark Residential Programs for Children

Melmark has provided residential supports for individuals under 21 since its founding over 60 years ago. The Krentel family had a young daughter with special needs that was living in an institution in another state. The family knew they could provide a home of love, support, and learning and brought her home. The Krentel family soon started supporting other children with special needs as well and were very successful in the mission of providing better care than that found within institutions of the time. The care model changed into a model of skill acquisition and learning through the years. In more recent years, the model is based upon evidenced-practices implemented by highly qualified professionals to increase best outcomes for the individuals served, all while maintaining the original legacy of love and compassion.

Melmark currently has capacity to support 55 children in a residential model. Thirty-six spots are funded through Medicaid funding through managed care organizations (MCO) and 19 are funded through school districts as part of their Individual Education Plan (IEP). All homes are licensed under the PA Title 55 Chapter 3800 regulations and the RTF homes are additionally certified through the Office of Mental Health and Substance Abuse Services (OMHSAS). All of the programs are designed for individuals with profound ASD, intellectual disabilities, and other neurodevelopmental disorders. These types of disorders most often present themselves early in life, with presenting symptoms remaining and impacting daily life for the individual throughout the lifespan. An individual residing in a Melmark children's residence must have a neurodevelopmental diagnosis, must have at least moderate developmental impact, and present a risk of harm to self or others. Most individuals have very limited cognitive and language abilities (e.g., no spoken language; limited ability to respond to spoken language), which individually are each known as risk markers for persistence of self-injurious behavior (SIB; Dimian & Symons, 2022). The individuals served in Melmark's residential program present with multiple risk markers for SIB. As discussed below, program design, intervention selection, and intensity are critical factors for positive treatment outcomes for individuals with profound autism and intellectual disabilities (Frazier, et al., 2024). The presence of active or primary mental health or psychiatric conditions (e.g., psychotic disorders, bipolar disorders, depressive disorders) are rule out criteria for Melmark's programs.

The goal of Melmark's RTF is to help each child attain the highest level of personal growth, achievement, and independence by decreasing challenging behaviors, increasing adaptive behaviors, and facilitating the reunification of the individual with his or her family in a less

restrictive environment. Melmark utilizes a multidisciplinary treatment team that utilizes best practices in the areas of applied behavior analysis (ABA), functional behavior assessment and functional life skills curricula. This includes psychiatry, 24-hour nursing, allied health (i.e., OT, PT, SLP), as well as behavior therapy and parent training. Using an interdisciplinary team approach, Melmark provides a safe, motivating and nurturing environment that facilitates individualized, goal driven, outcome-based services. This goal is achieved in partnership with the individual served, the family, Melmark's staff and in collaboration with external professionals and community providers and services.

The specific design of the service model at Melmark is best described as evidence-based and outcomes driven. Melmark's intervention philosophy is rooted in applied behavior analysis (e.g., behavior serves a purpose, assessment, objective treatment descriptions, objective data collection). Intervention techniques are based on a comprehensive understanding of the child served and the environmental factors that influence his/her behavior. Interventions may include any of the following empirically supported techniques: positive reinforcement, shaping, chaining, task analysis, discrete trial instruction, prompting strategies, redirection, de-escalation, incidental teaching, small group instruction, group activities, social skills training, desensitization, coping strategies, and other intervention strategies as indicated by each child's clinical needs and the relevant clinical literature. A sample of research and practice guidelines supporting the service model are provided in the reference section at the conclusion of the document, including a link to Melmark's published research and publications on Melmark's model of care. Link to Melmark's Attaining Excellence Document

The treatment planning process and Individual Support Plan (ISP) are both child-centered and family-focused. Melmark has also incorporated trauma informed care principles to be designated a "Trauma-Aware" provider. Goals and instructional methodologies are implemented within the residential, community, and family home settings, and when possible, within the educational setting. The ISP plan reflects the child's strengths and identifies prioritized goals and objectives, implementation of specific techniques to promote change and stated criteria for success and discharge. The treatment team also provides constant attention and sensitively to possible Aversive Childhood Experiences (ACSs). To ensure the safety and wellbeing of all individuals and staff members, through ongoing assessment and collaboration, treatment plans are adapted and modified to meet the needs of any individuals who may be exhibiting trauma responses or related behaviors. The ISP is typically updated on a semi-annual basis or more frequently if clinically indicated.

Robust treatment outcomes are accomplished with robust staffing ratios (i.e., 1 Bachelor level staff per 2 children is the minimum ratio); presence of professionally credentialed staff (e.g., nurses, occupational therapists, physical therapists, speech and language pathologists, board certified behavior analysts (BCBA), board certified behavior analysts – doctoral psychiatry); supervisor and professional staff presence on the floor training staff, supervising staff, and supporting individuals directly; and ensuring high quality physical resources are provided (e.g., home environment that matches a home in the community; access to adaptive technology). Caseloads for professional staff are small (e.g., 1 BCBA per 7 individuals) to allow for individualized assessment, treatment plan development, treatment implementation, and staff training. Professionals also implement individualized parent training protocols to facilitate

improved family relationships, teach parenting skills specific to the ASD population, family community participation, assess home environments for safety (i.e. PICA, bolting, etc.), successful home visits, and family reunification. Parents are expected to participate in parent training protocols on-site, in the community, and in their home. Virtual models (e.g., Zoom) are utilized for families limited by travel distance or restrictions.

Treatment activities are provided during all waking hours and are built upon an interdisciplinary model with a strong behavioral focus. Supervisors maintain an active and consistent presence in the treatment environment, supporting direct care staff in the highly individualized programs developed for the children served. The Behavior Support Plan (BSP) is the clinical platform guiding treatment during all waking hours, reflecting clinical input from Melmark's multidisciplinary clinical team. It is an integrated and dynamic document that is modified on a regular basis as clinical goals are addressed, or when alternative behavioral interventions are recommended and implemented.

Community integration is a critical component of residential service at Melmark. Melmark's goal is to provide a clinical platform that promotes active involvement in a child's home and community. Activities such as going out to eat, faith-based activities, job sampling, grocery shopping, shopping for and purchasing personal items, going for haircuts, attending movies or sporting events, are just some of the activities that are included in a typical week. The RTF program routinely has over 100 community access events per month, of which over 95% are successful.

In summary, the current Melmark RTF program serves individuals with different needs than individuals with behavioral needs. Given the difference in population, the program model is different. The current proposed regulations detail a program model for a different population, which likely fits their needs. Requiring providers to use an inappropriate service model that is contraindicated for individuals with documented needs for residential services will end poorly for the individuals (e.g., programs will close reducing overall capacity, programs will change the profile being served reducing capacity for certain individuals). There must be some opportunity for flexibility with regulations to match program design with individual support needs (e.g., waiver process and approval of program models with key features incorporated innovatively) but should not result in more administrative burden.

Comments Regarding IRRC Process

The IRRC provides guidance on the criteria utilized to evaluate proposed regulations (see https://www.irrc.state.pa.us/contact/faqs.cfm for further information). Three criteria stand out for the current regulation proposal: economic and fiscal impact on the public and private sectors; clarity, feasibility, and reasonableness of the regulation; and whether acceptable data is the basis of the regulation. Based upon information presented by the Department it is our conclusion these three criteria require additional information.

Economic and fiscal impact. Within the comments provided below in the 1330 and 5530 sections, financial information regarding the impact of rate setting, obtaining psychiatrists to fulfill mandatory positions, and impact of additional staffing requirements, is provided. In short, programs may have reduced ability to invest in supporting more individuals in need; larger

programs may experience an increased annual cost of $600,000 - $1,000,000 for psychiatrists; and staffing ratios must be richer than the minimums to meet treatment goals. Unfortunately, the Department does not evaluate, discuss, or provide recommendations for these aspects. They do discuss the minimal financial impact of the increased cost for accreditation purposes (i.e., $10,000) which underrepresents the potential financial impact.

Clarity, feasibility, and reasonableness of the regulation. The Department does not specifically address areas within this area. The utilization of psychiatrists is a useful example. The State of Pennsylvania issued finding regarding mental health care workforce shortages (2020-06-04 HR193_Mental Health Workforce.pdf).

> On page 21 it states: "Pennsylvania is among the 43 states struggling with a shortage of psychiatrists … According to the Bureau of Labor Statistics (BLS) there were over 25,000 psychiatrists nationwide in 2018 … most are employed in physician offices and hospitals … Pennsylvania had 1,140 … Based on 2017 survey data cited by the National Council for Behavioral Health (NCBH) the demand for psychiatry in the U.S. may outstrip supply anywhere from 6,090 to 15,600 psychiatrists in 2025."

Based upon this data supplied by the State of Pennsylvania, a need of 6,090 to 15,600 psychiatrists represents a 20% to 38% shortage of psychiatrists right now, and most are already employed in a setting where they are serving individuals in a higher aspect of the continuum of care (i.e., general hospital or psychiatric hospital). The proposed regulations will exacerbate the already present shortage, creating a large barrier of feasibility and reasonableness for the regulation.

Acceptable data is the basis of the regulation. The proposal from the Department describes the number of RTFs that are licensed, certified, or accredited and the number of children being served in an RTF (see the answer to question #10 on the regulatory analysis form). Some of the stated benefits are 1) streamline the licensure process; 2) adding requirements that specifically address the health, safety, and treatment needs residents; 3) quality of staff delivering service by changing staff qualifications, roles, and responsibilities; 4) increased minimum training standards for staff; 5) enhances staff ratio requirements; and 6) increases reportable and recordable incidents. It is our professional practice, research, and regulatory experience that when proposals for improvement are stated, it is based upon available data demonstrating that a problem exists warranting change for improvement. The Department should provide data to substantiate the claims of improvement areas and how the regulations will explicitly address those areas of need. Additionally, there should be feasibility data provided regarding factors such as staffing impacts for direct support professionals (DSP) and professional staff (i.e., there is a workforce shortage in healthcare and human service industries and these regulations require a workforce increase).

Federal Code for PRTF

General Comments

The Center for Medicaid Services (CMS) has provided guidance and reimbursement avenues for providers to exist as a PRTF, RTF or residential treatment center (RTC). In a memo dated February 16, 2007 CMS provided guidance about a continuum of care for psychiatric supports

and the difference between a PRTF, RTF, and RTC (see Department of Health & Human Services for a copy of the memo).

On page 2 a continuum of care is provided in the statement:

> A PRTF is to provide a less medically intensive program of treatment than psychiatric hospital or a psychiatric unit of a general hospital.

On page 3 clarification of the difference between a PRTF, RTF, and RTC is provided:

> RTFs or RTCs provide a mixed level of service to children who do not need the intensive services of a PRTF.

On page 3 clarification of what psychiatric disorders should be supported in a PRTF is provided:

> States can determine which psychiatric conditions would fall under this benefit and for which the State will reimburse payment for services rendered. For example, diagnoses may include paranoid schizophrenia, post-traumatic stress disorder, depression, and/or hyperactivity-attention deficit disorder. (Note: There is no listing for developmental disorders, which encompasses the ASD population.)

These statements make it clear that a continuum of care exists within the federal code and that multiple levels of residential care are available for individuals. Designation of different residential programs should be based upon the program model and intended support for individuals.

In addition to the CMS memo, CMS provides approximately 75 different Place of Service Codes (see Place of Service Code Set | CMS for additional information). Based upon the federal definition of inpatient psychiatric services (i.e., § 441.151) a PRTF is considered an inpatient psychiatric facility, which is assigned a place of service code 51. There are other residential service codes that are provided. For example, Melmark currently bills all RTF services under service code 56 – Psychiatric Residential Treatment Center. Based upon the CMS memo and service code list, it is possible for providers to receive Medicaid funds without being designated a PRTF. Providers can be designated an RTF or RTC, receive Medicaid funds through a MCO, and ensure the best outcomes are achieved for individuals needing the appropriate service models to meet the needs of their disability, in this case ASD. We strongly encourage the Department to clarify, as allowed in federal code and procedures, the continuum of residential care to include psychiatric hospitals, PRTFs, RTFs, and RTCs. The Department has an opportunity to better define residential services for children with complex needs, which is a known need in the State (see Youth-with-Complex-Needs-A-Blueprint-Workgroup-Report.pdf for additional information). Reducing the continuum of care by aggregating providers into a single provider type is not beneficial for individuals being served.

Although it is our view that applicability for the regulations do not and should not apply to our provider type, we feel it is important to support the Departments efforts. Therefore, we are providing additional public comments on the proposed regulations. Our comments are from the context of if we were required to become a PRTF and the potential impact on the individuals currently served in our RTF program.

Title 42, Chapter IV, Subchapter C, Part 441 Subpart D Inpatient Psychiatric Services for Individuals Under Age 21 in Psychiatric Facilities and Programs

We recognize the below comments are regarding federal code that is not necessarily open to public comment. Our intent is to provide comments on areas that allow flexibility of interpretation of state implementation.

§ 441.151.(a)(1) – Services are provided under the direction of a physician. The United States healthcare system is experiencing a crisis with physician shortages, including psychiatrists (Iroku-Malize, et al., 2023). Beyond policies and practices to support additional physicians, allowing other credentialed healthcare providers to meet practice needs is essential. For example, the State of Pennsylvania certifies psychiatric nurse practitioners, who have training in line with the physician oversight requirements. Where possible, regulatory clarifications for enhanced utilization of qualified healthcare professionals would reduce personnel requirements.

§ 441.151.(a)(2)(ii) – Accreditation by Joint Commission on Accreditation of Healthcare Organizations (JCAHO), Commission on Accreditation of Rehabilitation Facilities (CARF), or any other organization with comparable standards. Given the model description of Melmark's RTF program, the accreditation options provided do not align completely. There are accreditation options for providers with an applied behavior analysis (ABA) treatment model (e.g., Autism Commission on Quality (ACQ), Behavioral Health Centers of Excellence (BHCOE). We recommend the state provide guidance on how "other organizations with comparable standards" would be assessed so that organizations can choose an accreditation body that matches their program model.

§ 441.153 – Team certifying need for services. In the current program model MCO teams certify the need for services, and once completed send the certification (i.e., the referral) to providers for placement. It is our recommendation that this practice continues and should be specified within the state regulations. This would ensure compliance with proposed regulation § 1330.32.

§ 441.156 – Team developing the individual plan of care. The regulation generally recognizes several different professionals with a scope of practice that could satisfy the plan development. The regulations specify additional team members that should be present (i.e., social worker, nurse, occupational therapist (OT), master level psychologist). We request the state provide flexibility with accepted team members as there are several other disciplines that could support the plan development. Specifically, in addition to an OT, a speech language pathologist (SLP) and physical therapist (PT), with similar training, should be allowed to participate. Furthermore, a master's or doctoral level behavior analyst should be included in the category with a master's level psychologist, as they are primary providers of behavioral healthcare to the ASD population. Lastly, a master's level professional licensed in Pennsylvania as a Behavior Specialist should be included in the category with the master's level psychologist. These are professionals with training and expertise that can support the program model and conditions of participation outlined in Subchapter G, Part 483, Subpart G, but must be recognized by the state. Additionally, the ASD population served within the Melmark RTF and other RTFs is more varied than what is described within the regulations requiring a wider range of professionals trained in those presentations, assessments, interventions, etc.

Title 42, Chapter IV, Subchapter G, Part 483, Subpart G Condition of Participation for the Use of Restraint or Seclusion in Psychiatric Residential Treatment Facilities Providing Inpatient Psychiatric Services for Individuals Under Age 21

§ 483.352 – Drug used as a restraint. Under this definition a drug is considered a restraint if one of three criteria are met. The third criterion is that a drug is used and is not a standard treatment for the medical or psychiatric condition. As described above, Melmark supports individuals with ASD and IDD diagnoses. There are only two FDA approved drugs for irritability in ASD (i.e., risperidone and aripiprazole; Leclerc & Easley, 2015). The use of "off-label" prescriptions within the ASD and IDD service industry is standard, and this must be recognized. If this is not recognized and codified in regulation, the regulation treats standard drug usage within this population (e.g., a drug prescribed for daily use to reduce symptoms associated with ASD and IDD) as a restraint (see § 483.356 and 358), which requires additional processes for order, implementation, and follow-up.

§ 483.358 – Orders for the use of restraint or seclusion. Melmark is committed to utilizing positive interventions that support acquisition of adaptive behaviors that reduce the need for behaviors such as aggression or self-harm. As described above, Melmark serves individuals with limited language, limited safety skills (e.g., touching a hot stove, walking into a busy intersection, stranger danger), and high probability of self-injury (e.g., head banging, biting self, hits to eyes). These individuals are at higher risk of further life-long disability (e.g., loss of vision due to a detached retina, loss of cognitive function due to repeated head trauma) and death (e.g., walking into a busy intersection, drowning). Individuals served at Melmark have often failed other treatment options and are engaging in these types of harmful behaviors hundreds of thousands of times a day and persist across the lifespan. Despite positive approaches to treatment, there are times when safety concerns warrant more restrictive physical support procedures. The protocols within § 483.358 require a prescribing physician or other licensed practitioner to order restraint or seclusion, which limits timely application of safety protocols. There is a need for flexibility of this regulation. For example, § 483.356(a)(2) states no standing or as needed orders must be written, but § 483.358(g)(3) states the order must contain the length of time for use. The second statement seems to create an opportunity for broader orders of length of time (e.g., 30 days) whereas part of the required plan review process every 30 days the order could be reviewed and additional planning occur. Additionally, if the provider can demonstrate an organizational approach to protecting rights of the individuals, use of positive treatment approaches, and reduction of restrictive procedures it could provide additional flexibility. For example, Melmark already tracks every restrictive procedure, including restraints, conducts team reviews of progress and utilization every two weeks, has monthly safety review meetings to specifically review all restrictive procedures and restraints, and reports on outcomes to the Board of Directors. These processes reflect the importance of individual rights, balanced with their right to effective treatment and freedom from harm. Currently, there is no peer reviewed literature beyond physical intervention to interrupt immediate self-injury and severe aggressions that cause sever risk to oneself or others.

§ 483.364 & 368 – Monitoring of the resident in and immediately after seclusion and application of time out. Melmark has a policy that does not allow for the use of seclusion or time out. We

share this information as another example of our commitment to positive approaches to treatment and minimizing the use of restrictive procedures, and the need for additional flexibility as discussed in *§ 483.358.*

§ 483.376 – Education and Training. We support the language utilized in the federal code regarding demonstration of competency within training. Melmark utilizes evidence-based approaches to training and requires initial and ongoing demonstration of competency. We strongly suggest the department include the language of behavior skills training (BST) of staff. BST is an empirically supported training strategy that involves four main components: (a) instructions, (b) modeling, (c) rehearsal role play, and (d) performance feedback. This provides staff ample opportunities to practice target skills under the supervision in the treatment environment of an experienced and credentialed trainer (Parsons, Rollyson, & Reed 2012), (Lin et al, 2024).

State Code for PRTF

Chapter 1330

§ 1330.32 – Conditions for payment. As stated above in § 441.153, MCO teams certify the need for services, and once completed send the certification (i.e., the referral) to providers for placement. It is our recommendation that this practice continues and should be specified within the state regulations.

§ 1330.38 – Nonallowable costs. As proposed § 1330.38(9)(xxii) Nonallowable Costs defines personal hygiene items for children, youth or young adults receiving service in the PRTF as nonallowable costs. However, § 5330.83g requires PRTFs to provide the following personal hygiene items for each child, youth or young adult: (1) towels and washcloths, (2) toothpaste, (3) toothbrush, (4) comb or hairbrush, (5) shampoo, (6) soap, (7) feminine hygiene products, if needed (8) toilet paper, (9) deodorant, if needed, (10) body lotion, if needed. Per review of CMS guidance as well as Federal allowable cost provisions, personal hygiene items for individuals residing in a PRTF are not required to be classified as nonallowable costs. Per review of PRTF allowable cost provisions for several other states receiving federal funding for PRTFs, personal hygiene items are not specifically classified as PRTF nonallowable costs. Since personal hygiene items are required to be provided under § 5330.83(g) and there is no federal requirement for these costs to be classified as nonallowable, we propose subsection (9)(xxii) Personnel hygiene items be removed from the nonallowable costs provision of § 1330.38

§ 1330.39 – Annual cost reporting and independent audit. Code § 1330.39(a) requires RTFs that are licensed under Chapter 3800 and certified by the department to provide a projected cost report within 3 months of the publication date of the proposed rulemaking. We propose this time period be extended from 3 months to 6 months in order to provide additional time for an unaccredited RTF to more accurately quantify all of the projected program costs associated with the new § 1330 and § 5330 requirements including the cost of accreditation, additional personnel costs, additional training resources, and other cost necessary to comply with the new regulations.

§ 1330.40 – Rate setting. Per § 1330.40(a)(1) a cost report will be used for the calculation of a PRTF's per diem rate. Under the proposed timeline cost reports are submitted three months after fiscal year end and then the department has six months to review the cost report and accept it. Does this mean revised rate setting can be delayed for nine months? The cost of recruiting and retaining the highly skilled workforce necessary to obtain best outcomes for individuals with complex needs in an RTF increase every year due to the very competitive direct care workforce environment. In addition to wages, the cost of staff training, workers compensation, health and other allowable employee fringe benefits, general liability insurance, property insurance, vehicle insurance, food, supplies, utilities, among other allowable costs have a track record of increasing every year. For this reason, Melmark recommends the regulation requires the revised rate setting be applied retroactive to the beginning of the fiscal year in an attempt to keep per diem rates more current. In addition to using historic costs to determine future per diem rates, the rate setting should also allow a provision to have new incremental added to the rates to account for expected cost increases. Regulation § 1330.40 should not prevent MCO's from negotiating rates with PRTF's. Negotiated rates are necessary to support individuals with high activity and unique complex needs. Negotiating per diem rates with MCO's also provides the resources necessary to maintain capacity in highly inflationary periods or expand capacity to ensure that more high acuity individuals can receive life sustaining services. This is not possible with the proposed lagging cost-based rate setting process.

§ 1330.41 – Third-party liability. Code § 1330.41(a) requires a PRTF to utilize available third-party resources, including Medicare Part B, for services a child, youth or young adult receives while in the PRTF. Per Medicare.gov, Medicare Part B covers mental health visits with certain professionals and certain outpatient mental health services but Medicare Part B does not cover treatment in a PRTF. Does § 1330.41(a) mean that an RTF that does not currently participate in Medicare is required to participate in Medicare, despite PRTF being an uncovered service?

Chapter 5330

§ 5330.4(b) – Licensure and certificate of compliance. There is an allowance of 12 months for compliance with the regulation. Additional time for compliance is requested based upon the accreditation process that providers will need to complete. For example, accreditation by the Joint Commission can take 4-6 months to complete. That does not account for the preparation prior to starting the process, which will be occurring while providers are also altering systems of care to align with new regulations. Providers should be given one year to complete preparations and six months to complete the accreditation process. An allowance of 18 months to two years after the effective date is more reasonable for providers to comply with the requirement.

In addition to the provider license standards set forth in this code, providers also complete additional visits and evaluations with MCOs. A purpose set forth in this code is to streamline the process for provider qualification. We recommend the Department coordinate with MCOs to recognize the additional requirements (i.e., accreditation) and ensure there are not additional requirements established by MCOs or the Department.

§ 5330.4(c)(6) – Accreditation entity. As stated in the federal requirements above, the Department should provide clarity on the process for utilizing accreditation entities not listed in the regulations.

§ 5330.7 – Exemptions. The code allows for exemptions of certain provider types based upon the population served (i.e., providers licensed under Chapter 3800 or 5310). These providers also fall under Articles IX and X of the Human Services Code and certified by OMHSAS and OCYF. As described above, Melmark provides services to a population substantially different from the population typically served in PRTFs. The option to serve this population under Chapter 3800 is not viable given the funding structure in Pennsylvania. Specifically, Pennsylvania has opted to cost shift necessary residential care to the medical assistance (MA) funds versus allocating funds to local education agencies (LEA) to support the right to a free and appropriate education (FAPE), including 24-hour supports. Therefore, school districts rarely fund placement into a home licensed under the 3800 regulations. Individuals with profound ASD and IDD will be forced into a service model not designed for their needs based upon funding allocations. It is our recommendation that exemptions for providers serving individuals with ASD and IDD be considered given the program model differences needed for service provision. This would allow time for additional consideration and determination to further align care needs for this population.

§ 5330.12 – Coordination of services. The need to coordinate services across providers is essential for best outcomes of individuals served. The intent of this particular regulation is understood to help providers develop formal relationships to ensure this coordination of care. We have concern that it will not have the intended effect, but will result in administrative burden on the PRTF provider. For example, Melmark has sought to develop relationships with both hospitals and urgent care providers in locations close to our residential programs. External providers have been very hesitant to develop formal relationships with us given the population we serve. Specifically, they state a lack of understanding for supporting individuals ASD and IDD and that only emergency rooms or inpatient stays can provide basic support such as evaluation of presenting concerns like increased temperature, localized pain, etc. because the individual cannot speak. Additionally, in the rare occasion when a behavioral health crisis could not be supported in the facility and transfer to an inpatient setting was requested, the receiving entity often states there is nothing to be done because it is just symptoms of the diagnosis or the individual cannot consent for treatment given their communication limitations. The external provider has been unwilling to initiate a transfer of care for the purpose of acute psychiatric care.

We recommend the language be changed in three ways: first, that the provider must demonstrate ongoing attempts to develop relationships with the entities listed, but that in the absence of a formal agreement the provider will not be penalized. Second, the renewal of the agreement should be on an as-needed basis instead of annually; the language of the agreement should state an ongoing relationship unless formally discontinued in writing. Lastly, the list of service providers should be a recommendation, not exhaustive, and the provider should discuss what agreements are in place or being developed based upon the needs of the program.

§ 5330.12 – Reportable incidents. Providers are often licensed to serve multiple different individuals in various programs, typically all falling under Title 55 Human Services of PA Code.

Regulatory alignment for practices within the Title would reduce the administrative burden upon providers and the Department. Other licensed programs allow a 24-hour period for completion of external reporting of reportable incidents (e.g., mandated reporter, office of developmental programs [ODP] incident management bulletin) and parent notifications. Allowing 24-hours for reporting to the Department and parents is requested as the focus post incidents is to ensure safety of the individual(s), which can be resource intensive at times, and it creates consistency of standards across programs.

§ 5330.15 – Recordable incidents. As stated above in § 5330.12, 24-hour period for contacting parents for these incidents should be provided.

§ 5330.20 – Visits. PA Medical Assistance Bulletins 01-95-12 and 01-95-13 outlines the parameters for therapeutic leave for individuals residing in JCAHO and non-JCAHO accredited facility (e.g., leave of 12 hours or more counts is a day of leave; 48 total leave days per calendar year). It is requested that the regulations be clarified to specify if the procedures within the bulletins are still applicable under the new regulations.

§ 5330.31 – Rights. Thank you for ensuring the protection of individual rights via regulation. A listed right is communication in a language the individual understands. We are pleased that one additional modality was included – American Sign Language. As described above, Melmark supports individuals with ASD and IDD, often accompanied by very limited spoken language. Evidence-based support for individuals with limited language is the use of Augmentative and Alternative Communication (AAC) devices to support communication. Inclusion of these types of communication systems would reflect the diversity of individuals served in PRTFs. Additionally, the utilization of additional communication supports (e.g., interpreter, iPad) requires financial resources. Clarification of reimbursement on a per diem basis (i.e., submit for reimbursement each instance the service is utilized) or via the established daily rate (i.e., the provider should calculate cost as part of the daily rate) would be beneficial.

Melmark supports the right for all individuals to be gainfully employed. A listed right is that an individual should be paid for "any work the individual does for the PRTF". This right and language exists in other PA residential programs and has been interpreted to mean that an individual should not engage in daily tasks of the home such as sweeping their bedroom floor, washing their dishes, washing their laundry, etc. because it is "work for the provider". As found in the definition for manual restraint (i.e., *§ 5330.31)*, there is a clarifying statement that hands-on assistance needed to enable a child is not considered a manual restraint. A clarifying statement indicating that completion of house chores typically completed by children and youth residing with parents is not considered work requiring pay. Participation in daily living activities is often a treatment outcome for children and youth to be successful with transition to other levels of care. Additionally, completion of daily living activities provides a therapeutic context for the individuals.

§ 5330.41 – Supervision of staff. We commend the Department for incorporating supervisory practices into regulation. Direct contact BST between a supervisor and supervisee provide a context for improved outcomes for the individuals served (e.g., performance feedback processes improve employee skills) and can support retention of employees. We recommend that in

conjunction with minimum number of contacts, modality, and hours the Department consider adding language about utilization of evidence-based supervision practices. For example, Maguire et al., (2022) describes BST supervisory training and implementation within human service organizations, including linking training to mission, vision, and values; training supervisors to pinpoint expected behaviors; training expected behaviors initially and ongoing; and how to have tough conversations.

Another consideration of this requirement is the increased cost of staff. Ratios of staff and subsequent cost are often calculated based upon minimum needs of the program (see § 5330.41 – Staff requirements). Providing out of ratio time for staff requires that others be in ratio to ensure the continued minimum ratios, care, and availability to support periods of acute crisis.

§ 5330.41 – Staff requirements. The proposed minimum standards of staffing seem reasonable for a program where individuals possess basic safety, self-care, and communication skills. As described above, the individuals served in the Melmark RTF have much higher needs across all domains of life, which require higher levels of staffing ratios to ensure safety and positive therapeutic outcomes. Based upon information contained in the proposed Chapter 1330, it appears individual providers will have a continued process to be reimbursed at rates that support richer staffing ratios as long as it is justified by the overall program description and individual treatment needs. This flexibility with reimbursement practices is essential to ensure staffing decisions are based upon the needs of the individuals not dictated by regulation.

The minimum ratios needed to implement other regulatory standards for staff supervision (i.e., § 5330.41 – Supervision of staff) may make these minimum ratios higher. For example, if one mental health worker is completing the monthly face-to-face supervision meeting for one hour, they must be off ratio with individuals. The program needs to have an additional staff member to cover during supervision periods. There are multiple ways to provide this coverage, each having different therapeutic and financial pros and cons. As stated in the previous paragraph, flexibility with reimbursement practices to ensure the spirit of the regulation (i.e., sufficient staffing ratios, good supervisory practices, and best outcomes for the individuals) is required.

It is stated that during the overnight hours staff must perform visual observations of each individual every 15 minutes. We recognize the intent for maintaining safety of individuals. However, prescribing this level of care is not conducive to transitioning an individual to lower levels of care. For example, very few children experience 15-minute visual observations at home while sleeping or awake. Additionally, the visual observations might be contraindicated for some individuals (e.g., light sleeper, trauma history during night time). We recommend the regulation allow for an individualized pattern of visual observations throughout sleeping hours. The individualized pattern would be determined by the treatment team and documented in the treatment plan.

§ 5330.43 – Medical director, § 5330.44 – Treatment team leader, and § 5330.45 – Clinical director. As discussed in the above federal code section, the requirement of a medical director is potentially a problem given shortages of healthcare professionals and is reliant on a medical model of training, assessment, and intervention. Requiring the director to be a psychiatrist further exacerbates the concern given the shortage of these specialty training healthcare providers.

Additionally, it might be necessary to have two psychiatrists given the requirement for the treatment team leader to meet the same qualifications as a medical director. The federal code allows for flexibility of other healthcare providers to fulfill this role. For the medical director, we strongly encourage the Department to provide expanded parameters of licensure (e.g., any healthcare license) and training requirements (e.g., at least three years' experience), and that job duties would be commensurate with licensure and training. For the treatment team leader, expanded licensure parameters outside of healthcare (e.g., psychologist, board certified behavior analyst) are recommended.

We also encourage the Department to consider the need for all three positions (i.e., medical director, treatment team leader, and clinical director). There is a high potential for overlapping functions between the three positions (e.g., oversight of the program, individual treatment decisions), and higher staffing costs that are not necessary. Assuming three different professionals (e.g., two psychiatrists and one psychologist) are needed given the scope and size of the program the overall cost for three professionals is close to one million dollars (e.g., psychiatrist #1 salary = $260,000; psychiatrist #2 salary = $260,000; psychologist #1 salary = $155,000; benefits for all employees $225,000).

The list of qualified professionals to fulfill the clinical director should be expanded to include a licensed behavior specialist and a board certified behavior analyst. Both of these professionals complete educational and experiential requirements to fulfill the clinical director requirements.

§ 5330.66 – Ventilation. Clarification is needed for the requirement that a window "must be securely screened when open." Other regulations require screens to be present for all windows, but the "securely" adjective is new. Examples and non-examples would be helpful.

§ 5330.142 – Treatment plan. The proposed regulation states a multi-disciplinary assessment must be completed within 48 hours of admission. While this may be appropriate for populations with more acute psychiatric needs, a 48-hour period is relatively short to complete assessments by multiple professionals for ASD / IDD individuals with complex needs. One aspect of assessment validity for this population is the development of a therapeutic relationship, which takes time. Given the complexity of individuals being served in a PRTF and often the lengthy history of treatment failure, engaging in an assessment process that enhances previous assessments (i.e., an assessment is required prior to PRTF admission), is individualized, and supportive of the individual, additional time should be allowed. Melmark utilizes a formal screening and admission process that aligns with these expectations but is completed across a 30-day period (i.e., 15 days prior to admission and 15 days post admission). We recommend the Department allow for providers to have a policy and procedure that describes the initial assessment process is completed within the initial 30-day period and informs development of a treatment plan.

The proposed regulation states a psychiatric evaluation must be completed within 7 days of admission. As detailed in the comments for federal code *§ 441.153*, a determination of eligibility is conducted prior to admission to a PRTF, which includes a psychiatric evaluation. We recommend the Department consider allowing providers to update the initial psychiatric

evaluation determining eligibility for placement be updated within the first 30 days of placement and in conjunction with the treatment plan development.

Pennsylvania utilizes MCOs to administer Medicaid programs, including a PRTF. As indicated in the report from the Blueprint Workgroup (see Youth-with-Complex-Needs-A-Blueprint-Workgroup-Report.pdf for additional information), different processes and forms across MCOs creates continuity of care issues and access issues for children with complex needs, and contributes to provider administrative burden. We recommend the Department provide a uniform assessment and treatment plan template that incorporates all expected elements into the template. This was a recommendation from the Blueprint Workgroup as well.

§ 5330.145 – Treatment services. The first requirement of treatment is to "ensure the physical and psychological well-being of the child". As discussed above in the federal code (see comments for § 483.358), the requirements for restrictive procedures are overly prescriptive and present very real challenges to meeting this requirement. Additionally, if the ability to individualize care, including restrictive procedure use, is prescribed it defeats the purpose of individualized assessment and treatment planning to meet individual "psychological, social, behavioral, medical, recreational, developmental needs, and traumatic experiences". If the Department cannot specify a continuum of care that recognizes various program models across multiple different populations, it will be difficult to support individuals with ASD and IDD in a manner that keeps them safe. Melmark will be faced with altering its program model to serve a different population or discontinuing its current program, both of which further harm individuals with ASD and IDD, and severe behavior disorders.

Requiring participation in certain therapy modalities (e.g., individual therapy, group therapy) and minimum hours (e.g., individual therapy for 1 hour per month) removes the ability for a provider to develop a unique program model and from adapting it to meet the individual needs of individuals. We recognize the Department is responsible for oversight and integrity with funds, but prescribing treatment models in this detail may prevent providers from innovative approaches to treatment, innovative approaches to care models to address acute care needs, etc. Furthermore, the definitions of these should be expanded to include ABA therapy such as social skills groups, discrete trial training, and parent training. These are evidence-based practices (e.g., Mayville & Mulick, 2011) for individuals with ASD and should be recognized for this population in place of traditional therapy. We recommend the Department establish broader expectations of service delivery in

§ 5330.151 – Transportation. In code § 5330.42, the minimum staffing ratios are one staff per six individuals. Based upon this code, a richer ratio is required if supporting the individuals in the community (i.e., one employee to three individuals). Additionally, the driver of the vehicle cannot count toward the ratio. The richer ratios for community participation will present a barrier to community participation. For example, if a provider has a 12 bed PRTF, they will need two staff for the minimum ratio requirements in the residence (and the supervisory positions). To support therapeutic goals in the community for three individuals at least two more staff must be present (i.e., driver; staff to provide 1:3 ratio in the community), while the two original staff remain at the residence (i.e., two staff are needed to meet the minimum requirements for the remaining 9 individuals). In practice, if a PRTF is going to include community integration goals

into treatment for individuals, they will need to staff all hours at a 1:3 ratio, which will increase staffing costs. Allowing the ratio to be 1:6 during transport or counting the driver for community visits reduces the additional staff from two to one (i.e., 3 staff are needed to support the community visit instead of four staff).

Per § 5330.151(e) a manual restraint is not allowed during transport. This regulation makes an assumption that emergencies or acute crises do not happen during transport and removes response options that could have very negative outcomes for individuals. As described above, Melmark serves many individuals that engage in serious self-harm and have limited safety skills. If positive and less restrictive techniques do not deescalate a situation it would present imminent risk of harm to the individual to not further intervene. Many crisis programs recognize the varied contexts in which an acute crisis might occur and provide supports for those contexts. It is our recommendation that providers be allowed to demonstrate training for utilization of manual restraints that allows them to be used in the context as necessary.

§ 5330.161-170 – Medication. As stated above in § 5330.12, providers are often licensed to serve multiple different individuals in various programs, typically all falling under Title 55 Human Services of PA Code. Regulatory alignment for practices within the Title would reduce the administrative burden upon providers and the Department. Aligning medication handling, administration, etc. with other state requirements (see Medication Administration Training Program | Department of Human Services | Commonwealth of Pennsylvania for additional information) is recommended.

Per code § 5330.166(c), if an individual refuses a medication the team leader must be informed within one hour of the medication refusal. Providers often develop standard protocols for missed medications, regardless of the reason. The standard protocols allow licensed professionals to make practice decisions, within their scope of practice and competence. It is recommended that this prescriptive requirement be replaced with a broader expectation that treatment teams review the medication administration history minimally during the required monthly review and adjust the treatment plan as a needed.

Per code § 5330.167, if an adverse reaction or a non-adverse reaction to a medication occurs the family must be notified within one hour or 12 hours respectively. As stated above in § 5330.12, when reporting standards are individualized for different types of events or across different service models it creates confusion and missteps. Any reportable incident is recognized as serious, warranting communication with partners. Providers are ensuring the health and safety of individuals at these moments and often communicate with partners, including families, very quickly. We recommend a uniform reporting period of 24 hours for all incidents.

§ 5330.181-190 – Restrictive procedures. As discussed above in § 483.358 Melmark is committed to utilizing positive interventions that support acquisition of adaptive behaviors that reduce the demonstration of behaviors such as aggression or self-harm. Individuals served at Melmark have limited language, limited safety skills (e.g., touching a hot stove, walking into a busy intersection, stranger danger), and high-probability of self-injury (e.g., head banging, biting self). These individuals are at higher risk of further life-long disability (e.g., loss of vision due to

a detached retina, loss of cognitive function due to repeated head trauma) and death (e.g., walking into a busy intersection, drowning). Despite positive approaches to treatment, there are times when safety concerns warrant more restrictive procedures. The protocols within § 5330.181-190 require a prescribing physician or other licensed practitioner to order restraint or seclusion, which limits timely application of safety protocols. There is a need for flexibility of this regulation. Providers should demonstrate an organizational approach to protecting rights of the individuals, use of positive treatment approaches, and reduction of restrictive procedures. For example, Melmark already tracks every restrictive procedure, including restraints, conducts team reviews of progress and utilization every two weeks, has monthly safety review meetings to specifically review all restrictive procedures and restraints, and reports on outcomes to the Board of Directors. This type of cohesive decision-making, implementation, and review fit key factors recommended by the American Psychiatric Association (2021). These processes reflect the importance of individual rights, balanced with their right to effective treatment and freedom from harm. Based upon § 5330.231 flexibility regarding § 5330.181-190 might be accomplished through a waiver of those regulations. According to Moore and colleagues (2024), factors associated with successful treatment of self-injurious behaviors are where treatment is provided (e.g., versus home) and by whom (e.g., therapist versus a parent), supporting the need for a continuum of care options for individuals with profound ASD and IDD.

Conclusion

As stated above, we believe CMS has provided the context for a continuum of residential care (e.g., psychiatric hospital, inpatient, PRTF, RTF, partial hospitalization) for individuals, all of which allow providers to reimbursed with federal Medicaid funds. The Department has the opportunity to enhance the continuum of care in Pennsylvania for children with complex needs (see Youth-with-Complex-Needs-A-Blueprint-Workgroup-Report.pdf for additional information). We strongly encourage the Department to clarify, as allowed in federal code and procedures, the continuum of residential care to include psychiatric hospitals, PRTFs, RTFs, and RTCs. Reducing the continuum of care by aggregating providers into a single provider type is not beneficial for individuals being served. Or, even worse, exacerbating the problem by reducing the number of providers.

We thank you for the opportunity to support the Department through the process of modifying its regulations and hope that our comments are supportive of the process. We would make ourselves available for any further discussion.

Respectfully submitted,

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