IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF IOWA
CENTRAL DIVISION

UNITED STATES OF AMERICA, Plaintiff, v. STATE OF IOWA, Defendant.	Civil No. 4:22-cv-00398

JOINT MOTION FOR ENTRY OF CONSENT DECREE

Plaintiff, United States of America ("United States"), and Defendant, the State of Iowa ("State"), hereby jointly and respectfully request that this Court enter the proposed Settlement Agreement and Consent Decree ("Decree") as an order of this Court, making it a consent decree. In support of their motion, the Parties rely on the arguments made in their Memorandum of Law in Support of Joint Motion for Entry of Consent Decree (Attachment A), and refer the Court to the Notice Regarding Investigation of Glenwood Resource Center (Attachment B), the proposed Decree (Attachment C), and proposed Order (Attachment D). The Agreement would resolve litigation initiated by the United States with the filing of a Complaint pursuant to the Civil Rights of Institutionalized Persons Act, 42 U.S.C. § 1997.

Respectfully submitted this 1st day of December, 2022,

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CERTIFICATE OF SERVICE

I hereby certify that, on this 1st day of December, 2022, the foregoing document, filed through the ECF system, will be sent electronically to the registered participants as identified on the Notice of Electronic Filing.

/s/David L.D. Faith II
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Attachment A

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF IOWA
CENTRAL DIVISION

UNITED STATES OF AMERICA, Plaintiff, v. STATE OF IOWA, Defendant.	Civil No.

MEMORANDUM OF LAW IN SUPPORT OF JOINT MOTION FOR ENTRY OF CONSENT DECREE

Plaintiff, United States of America ("United States"), and Defendant, the State of Iowa ("State"), respectfully request that this Court enter as an order of this Court the Settlement Agreement ("Agreement") submitted with the Parties' Joint Motion for Entry of Consent Decree, making the Agreement a consent decree. The Agreement would resolve litigation initiated by the United States with the filing of a Complaint pursuant to the Civil Rights of Institutionalized Persons Act, 42 U.S.C. § 1997 (CRIPA). The Parties seek entry of this Agreement to ensure that the agreed-upon comprehensive measures to reform the conditions at Glenwood Resource Center ("Glenwood" or GRC), an institution for individuals with intellectual/developmental disabilities (IDD), are implemented fully and faithfully. In accordance with Paragraphs 267-82 of the Agreement, the Parties request that the Court retain jurisdiction over the Agreement for the purpose of enforcing its terms until the State has achieved substantial compliance, as defined by this Agreement, and maintained that compliance for one year.

In its Complaint, the United States alleges that the State engages in a pattern or practice of violating the federal rights of the residents of GRC by placing them at serious risk of harm, by subjecting them to (1) harmful and uncontrolled human subject experiments; (2) inadequate medical and nursing care, physical and nutritional management, and behavioral health care; (3) needless and harmful restraint practices; and (4) incidents causing needless physical injury. The Complaint also alleges that the State's deficient policies, staffing, training, and safety and oversight mechanisms subject GRC residents to a serious risk of harm. The Parties agree that the changes outlined in the Agreement will address the systemic deficiencies that contributed to the constitutional violations. The Parties hereby agree and stipulate to the Court's entry of all aspects of this Agreement in resolution of the United States' CRIPA Complaint against the State of Iowa.

I. Background

On November 21, 2019, the United States notified the State of Iowa and GRC leadership of its intention to investigate conditions at GRC. The United States' investigation included on-site inspection of GRC with expert consultants; interviews of State staff, residents, and residents' guardians; and extensive review of documents such as policies, procedures, forms, incident reports, and medical records. On December 22, 2020, the United States provided the State a CRIPA Notice of the results and recommendations from this investigation. This Notice is submitted with the Motion for Entry of Consent Decree. In the Notice, the United States found reasonable cause to believe that the State violates the Fourteenth Amendment rights of GRC residents by subjecting them to unreasonable harm and risk of harm.[1]

[1] The United States continued to investigate whether the State violates the rights of Glenwood and Woodward Resource Center residents with IDD under Title II of the Americans with Disabilities Act. The United States issued a second Notice on December 8, 2021, concluding that there is reasonable cause to believe the State violates Title II by failing to provide services to qualified people with IDD in the most integrated setting appropriate to their needs.

Following the release of the CRIPA Notice, the Parties engaged in extensive negotiations to address and resolve the United States' findings. The United States was assisted by expert consultants who were involved in the investigation, and the State was assisted by GRC and Department of Human Services[2] leadership, to help inform the negotiations and ensure the resulting Agreement would correct the constitutional deficiencies in a way the State can achieve. Both Parties also conducted separate town hall meetings with GRC parents and guardians, and spoke with other stakeholders. The negotiations and input resulted in the Agreement, which mandates reforms to remedy the constitutional violations alleged in the Complaint. By implementing this Agreement, the State will deliver services at GRC to individuals with IDD in a manner that complies with the Constitution.

II. The Agreement Satisfies All Requirements for Entry as a Court Order

Entry of the Agreement as a consent decree is appropriate because the Agreement is fair, reasonable, and adequate; is consistent with the statutory objectives of CRIPA; and is in the interest of the Parties and the public. District courts substantively review settlement agreements and have discretion over whether to enter them as consent decrees. *E.E.O.C. v. Prod. Fabricators, Inc.*, 666 F.3d 1170, 1172-73 (8th Cir. 2012). Still, the Eighth Circuit has recognized that district courts are guided by a clear policy encouraging settlements. *Id.*; *see also United States v. City of Waterloo*, No. 15–CV–2087–LRR, 2016 WL 254725, at *3 (N.D. Iowa Jan. 20, 2016) (this policy "has particular force where, as here, a government actor committed to

The Parties have agreed to negotiate in good faith regarding additions to the Agreement to address the December 8, 2021, Notice, and will seek to amend the Agreement before this Court if those negotiations are completed successfully. The Parties submit that proceeding now to implement the reforms identified in the Agreement is warranted, given the severity of the alleged violations, while the Parties continue negotiations to address the remainder of the United States' findings.

[2] The Iowa Department of Human Services—since merged into the Department of Health and Human Services—runs the state Resource Centers.

the protection of the public interest has pulled the laboring oar in constructing the proposed settlement"). In determining whether to approve a proposed consent decree, "the trial court is to review the settlement for fairness, reasonableness, and adequacy." *Prod. Fabricators, Inc.*, 666 F.3d at 1172 (quotation omitted). The court also reviews to ensure the agreed-upon terms further statutory objectives. *See id*.

a. The Settlement Agreement is Fair, Reasonable, and Adequate

In evaluating a consent decree's fairness, the court considers both procedural and substantive fairness. *City of Waterloo*, 2016 WL 254725, at *4 (citations omitted). Procedural fairness turns on whether the parties were "negotiating in good faith and at arm's length." *Id.* (citing *United States v. BP Amoco Oil*, 277 F.3d 1012, 1020 (8th Cir. 2002)). To assess this factor, courts "should ordinarily look to the negotiation process and attempt to gauge its candor, openness, and bargaining balance." *Id.* (citation omitted). Here, the Parties "spent a considerable amount of time, effort, and expense negotiating a settlement." *United States v. Dico*, 516 F. Supp. 3d 839, 847 (S.D. Iowa 2021). Negotiations lasted from April 2021 through May 2022, with the most intense focus in the winter and spring of 2022. Both Parties were ably represented by experienced counsel. As noted above, expert consultants familiar with GRC and leaders within GRC and the Iowa Department of Health and Human Services also contributed substantively to these negotiations. Neither Party relied entirely on the other to formulate remedial measures, or the terms of the decree. *See City of Waterloo*, 2016 WL 254725, at *4. Instead, the Agreement is the result of intensive work and good-faith negotiations by both Parties.

Courts evaluating substantive fairness focus on "concepts of corrective justice and accountability: a party should bear the cost of the harm for which it is legally responsible." *Id*.

(citation omitted). Here, the State is responsible for running GRC in a way that protects the constitutional rights of its residents. The United States has alleged the State failed in this duty, and the State now bears the costs for both fixing the institution while it remains open and helping its residents to transition to other settings. The Agreement is substantively fair because the State has sole legal authority over GRC, including at the time the alleged violations of federal law occurred.

Finally, to determine whether a proposed injunction is reasonable and adequate, courts evaluate "(1) the basic legality of the proposed injunction; (2) whether the terms of the proposed injunction, including its enforcement mechanism, are clear; (3) whether the proposed injunction reflects a resolution of the actual claims in the complaint; and (4) whether the proposed injunction is tainted by improper collusion or corruption of some kind." *Goyette v. City of Minneapolis*, No. 20-cv-1302 (WMW/DTS), 2022 WL 370161, at *2 (D. Minn. Feb. 8, 2022) (citations omitted); *see also Dico*, 516 F. Supp. 3d at 848 ("the reasonableness inquiry is primarily concerned with the probable effectiveness of proposed remedial measures") (citation omitted).

The Parties' Agreement to address conditions at GRC is reasonable and adequate. As injunctive relief is "an appropriate form of relief in cases asserting violations of constitutional rights," *Goyette*, 2022 WL 370161, at *4, the Agreement is lawful. The terms are the result of several months of negotiation between the Parties and are informed by the prior experience of both Parties in consent decree compliance, and the Agreement is clear about how it may be enforced. Under Paragraph 6, the Agreement is "enforceable only by the Parties and the Court." Paragraphs 266 through 272 further clarify how such enforcement would occur, including a requirement that the United States notify the State of an intent to initiate enforcement

proceedings and that the Parties attempt first to resolve the dispute. The Agreement resolves the claims in the complaint, covering the human subjects experiments; clinical care; restrictive interventions; incident management; and other topics related to services provided at GRC. The Agreement further provides for rigorous State oversight of the facility, and for a process to help residents transition to other locations consistent with their informed choice, needs, and preferences.

These proposed remedial measures, if implemented fully, are likely to resolve the underlying constitutional deficiencies and prevent their recurrence. Finally, the Agreement is not tainted by collusion: The Parties were represented by experienced counsel, assisted by others familiar with GRC and the State system, and informed by the United States' findings regarding GRC conditions. This adversarial posture during negotiations, with expertise on both sides, provides further assurance that the Agreement meets the legal requirements of a settlement.

b. The Agreement is Consistent with the Goals of CRIPA and is in the Interest of the Parties and the Public

The Agreement is consistent with the CRIPA statute, whereby Congress has authorized the Attorney General to bring suit when there is reasonable cause to believe that, as here, a State "is subjecting persons residing in or confined to an institution . . . to egregious or flagrant conditions which deprive such persons of any rights, privileges, or immunities secured or protected by the Constitution or laws of the United States causing such persons to suffer grievous harm, and that such deprivation is pursuant to a pattern or practice of resistance to the full enjoyment of such rights, privileges, or immunities . . . ." 42 U.S.C. § 1997a. The United States' CRIPA Notice outlined the results of its intensive investigation and found reasonable cause to believe that the conditions at GRC violate the Fourteenth Amendment rights

of GRC residents. The Agreement's substantive provisions are designed to address the allegations in the Complaint, as well as the causes of the alleged unlawful conduct.

A consent decree is also in the Parties' and in the public interest. Indeed, the Eighth Circuit has observed that "[c]ontinuing jurisdiction is the norm (and often the motivation) for consent decrees. . . . A consent decree offers more security to the parties than a settlement agreement where the only penalty for failure to abide by the agreement is another suit." *Prod. Fabricators, Inc*., 666 F.3d at 1173 (citations omitted). Here, the Agreement also furthers the public interest in correcting unconstitutional conditions at a publicly financed institution and in increasing transparency, by requiring public reporting and stakeholder engagement through the life of the Agreement.

In sum, the Agreement is an appropriate resolution of the issues raised by the CRIPA Notice, because voluntary compliance with a negotiated agreement overseen by a court is more likely to expeditiously accomplish agreed-upon goals than forced compliance with court orders imposed at the end of contested, protracted, and costly litigation.

III. Conclusion

For the foregoing reasons, the Parties respectfully move this Court to enter the Settlement Agreement as an Order of the Court.

Respectfully submitted this 1st day of December, 2022,

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Attachment B

INVESTIGATION OF THE GLENWOOD RESOURCE CENTER

United States Department of Justice
Civil Rights Division

United States Attorney's Office
Southern District of Iowa

December 22, 2020

TABLE OF CONTENTS

I. SUMMARY

The United States Department of Justice (DOJ) provides notice, pursuant to the Civil Rights of Institutionalized Persons Act (CRIPA), 42 U.S.C. § 1997b, that there is reasonable cause to believe that (1) the conditions at Glenwood Resource Center ("Glenwood"), a state-run, residential facility for individuals with intellectual/developmental disabilities (IDD), violate the Fourteenth Amendment, and (2) the violations are pursuant to a pattern or practice of resistance to the full enjoyment of rights protected by the Fourteenth Amendment.

Consistent with the statutory requirements of CRIPA, we write this Notice to advise Iowa of the Department's conclusions with respect to constitutional violations, the facts supporting those conclusions, and the minimum remedial measures necessary to address the identified deficiencies. Specifically, the United States provides notice that Iowa operates Glenwood in a manner that has subjected residents to unreasonable harm and risk of harm, in violation of their Fourteenth Amendment rights, by exposing them to:

- Uncontrolled and unsupervised physical and behavioral experimentation;
- Inadequate physical and behavioral healthcare; and
- Inadequate protections from harm, including deficient safety and oversight mechanisms.

DOJ continues to investigate whether the right of residents at Glenwood and the State's other residential facility for people with IDD, Woodward Resource Center ("Woodward"), to receive services in the most integrated setting appropriate under the Americans with Disabilities Act (ADA) is being violated.

DOJ does not serve as a tribunal authorized to make factual findings and legal conclusions binding on, or admissible in, any court, and nothing in this Notice should be construed as such. Accordingly, this Notice is not intended to be admissible evidence and does not create any legal rights or obligations.

II. INVESTIGATION

On November 21, 2019, DOJ notified Iowa of its intent to conduct this investigation. DOJ conducted two onsite visits of Glenwood, as well as extensive meetings by videoconference. During these onsite visits and videoconference calls, DOJ attorneys and expert consultants conducted dozens of interviews of current and former Glenwood staff and management, Iowa Department of Human Services (DHS) leadership, and representatives of several State agencies that oversee Glenwood in some capacity. DOJ attorneys and consultants also interviewed and observed Glenwood residents and reviewed thousands of documents produced by the State.

III. BACKGROUND

Iowa's DHS operates Glenwood through its Division of Mental Health and Disability Services (MHDS). As of December 2019, Glenwood housed 195 residents. Glenwood's residents are individuals who have an IDD, along with behavioral and/or medical conditions that

are often complex and chronic. Glenwood provides medical services, nursing services, physical and occupational therapy, psychiatric services, psychological services, residential, programming and other services to these residents.

A number of other state agencies also have oversight of Glenwood, including: the Department of Inspections and Appeals (DIA) (which licenses Glenwood), the Department of Administrative Services (DAS) (which performs human resources, procurement, accounting, and general administrative services for all state agencies), the State Auditor's Office (charged with auditing the financial operations of Iowa's state and local governments), and the Office of the Governor. In addition, licensed staff at Glenwood are subject to regulation and oversight by bodies such as the Board of Medicine, Board of Nursing, and Board of Pharmacy.

DOJ has investigated conditions at Glenwood and Woodward before. In 2002, DOJ notified Iowa of its conclusion that conditions at Glenwood and Woodward were constitutionally deficient. Iowa and the United States entered a Settlement Agreement to guide reforms at Glenwood and Woodward in 2004. Iowa came into compliance with the Settlement Agreement, which then terminated, in 2010. However, as described below, conditions precipitously deteriorated at Glenwood in recent years.

Between termination of the Settlement Agreement in May 2010 and the opening of DOJ's investigation in November 2019, Glenwood has had three superintendents and three acting superintendents. Glenwood did not continue all of the policies, procedures, and programs that had been instrumental in obtaining compliance with the Settlement Agreement, though the extent to which DHS was aware of, or approved of, these changes is unclear. After a disturbing set of allegations of abuse and neglect, some of which resulted in criminal charges against Glenwood staff, *see infra* Section IV.D, Glenwood's most recent superintendent, Dr. Jerry Rea, took over the position in September 2017. He accelerated the pace of change away from polices, practices, and procedures that had been required to demonstrate compliance with the Settlement Agreement and instigated research and experiments on Glenwood residents. What had already been a facility plagued by poor communication and integration among departments became even more dysfunctional. The quality of care declined as Glenwood leadership, managers, supervisors, and staff had to choose between, as a staff person told us, watching their backs and watching their clients. This decline in care was facilitated by a DHS Central Office that was unwilling, unable, or both, to recognize and address the problem. At the end of December 2019, about a month after our investigation began, Dr. Rea was terminated for what the State described as a "mounting list of disregard for policies and procedures."[1]

IV. VIOLATIONS IDENTIFIED

DOJ has reasonable cause to believe that the State fails to protect residents from harm, including by conducting unregulated experiments on human subjects, failing to provide

[1] Days after DOJ's first onsite visit to Glenwood, the Superintendent of Woodward Resource Center was assigned as Interim Superintendent of Glenwood. She was recently named Superintendent of both Centers. She is referred to in this Notice as the Interim Superintendent. The current DHS Director arrived at the agency approximately three weeks before we notified the State of this investigation.

constitutionally adequate medical and behavioral health care at Glenwood, and utilizing unnecessary physical restraints, all of which have subjected residents to serious harms and risks of harm.

Residents of state-run facilities have a constitutional right to "conditions of reasonable care and safety," *Youngberg v. Romeo*, 457 U.S. 307, 324 (1982); *Beck v. Wilson*, 377 F.3d 884, 890 (8th Cir. 2004), and to be reasonably protected from harm. *DeShaney v. Winnebago Cnty. Dep't of Soc. Servs.*, 489 U.S. 189, 200 (1989) (explaining that if the state "fails to provide for [a resident's] basic human needs—*e.g.,* food, clothing, shelter, medical care, and reasonable safety—it transgresses the substantive limits of state action set by . . . the Due Process Clause"); *Norfleet v. Ark. Dep't of Human Servs.*, 989 F.2d 289, 291-92 (8th Cir. 1993). This includes a right to adequate health care, *see, e.g.*, *Dadd v. Anoka Cnty*., 827 F.3d 749, 756 (8th Cir. 2016); *Hall v. Ramsey Cnty*., 801 F.3d 912, 920 (8th Cir. 2015), and freedom from unreasonable bodily restraints, *Youngberg*, 457 U.S. at 321; *Beaulieu v. Ludeman*, 690 F.3d 1017, 1031 (8th Cir. 2012).

These rights are violated by conduct that shocks the conscience. *Hawkins v. Holloway*, 316 F.3d 777, 780 (8th Cir. 2003). In this context, whether conduct shocks the conscience is measured by whether the conduct "is such a substantial departure from accepted professional judgment, practice, or standards as to demonstrate that the person responsible actually did not base the decision on such a judgment." *Youngberg*, 457 U.S. at 323; *see also id.* at 321-22 ("Persons who have been involuntarily committed are entitled to more considerate treatment and conditions of confinement than criminals whose conditions of confinement are designed to punish.").[2]

The state also owes Glenwood residents a duty to protect them from risk of harm created by the state. *See Burton v. Richmond*, 370 F.3d 723, 727 (8th Cir. 2004) (explaining that, per one theory of liability under the substantive due process clause, "the state may owe a duty to protect individuals if it created the danger to which they become subject"). "If the state acts affirmatively to place someone in a position of danger that he or she would not otherwise have faced, the state actor, depending on his or her state of mind, may have committed a constitutional tort." *S.S. v. McMullen*, 225 F.3d 960, 962 (8th Cir. 2000).

The Fourteenth Amendment violations described in this Notice establish a pattern or practice of constitutional violations under CRIPA. A pattern or practice is "more than the mere occurrence of isolated or 'accidental' or sporadic discriminatory acts." *Int'l Bhd. of Teamsters*, 431 U.S. 324, 336 (1977). Instead, it is "the regular rather than the unusual practice." *Id. See Equal Emp't Opportunity Comm'n v. Product Fabricators, Inc.*, 666 F.3d 1170, 1173 (8th Cir. 2012) (citing *Teamsters*).

[2] In the Eighth Circuit, constitutional claims of inadequate medical care are analyzed under the deliberate indifference standard. *Scott v. Benson*, 742 F.3d 335, 339 (8th Cir. 2014). Thus, as to medical care, this Notice assesses Iowa's actions under the deliberate indifference standard. However, the distinction is not determinative because Iowa's conduct violates both the deliberate indifference standard and the professional judgment standard.

A. Glenwood Conducted Experiments on Its Residents Without Consent and Without Complying with Applicable Safety, Ethics, and Research Safeguards

Standard protections related to human subjects research are an outgrowth of the persistent history of coercive or unconsented experimentation on people with IDD in institutional care. Human subjects research regulations protect and promote "respect for persons," one of three fundamental ethical principles for all human subjects research.[3] Respect for persons "requires that individuals be treated as autonomous agents and that the rights and welfare of persons with diminished autonomy be appropriately protected."[4] This respect is manifested "in the practice that individuals should participate in research voluntarily and be given enough information to make an informed decision about whether to participate."[5] A federally mandated and universally accepted procedure for ensuring respect for persons in human subjects research is an Institutional Review Board (IRB) to review and approve or disapprove research activities. IRBs may only approve research when it determines that risks to human subjects are minimized, including by "using procedures that are consistent with sound research design," "risks to subjects are reasonable in relation to anticipated benefits," and, for research involving subjects "likely to be vulnerable to coercion or undue influence, such as . . . individuals with impaired decision-making capacity," "additional safeguards have been included in the study to protect the rights and welfare of these subjects."[6]

In addition to ensuring risks are appropriately managed, IRBs also must require that informed consent will be sought, obtained, and documented. Informed consent must include, among other elements, clear disclosure that participation is voluntary, that refusal to participate will involve no penalty, and that a participant can decide to withdraw at any time without penalty. The requirement of informed consent is "one of the central protections" in human subjects research, in that it protects the most intimate and fundamental ability of individuals to be "given the opportunity to choose what shall or shall not happen to them."[7] State-sponsored research conducted on individuals without their consent violates the Fourteenth Amendment. *See e.g.*, *In re Cincinnati Radiation Litig.*, 874 F. Supp. 796, 810-11, 814 (S.D. Ohio 1995) (finding that a medical center exposing cancer patients to large amounts of radiation without consent as part of a Department of Defense research project gave rise to a due process claim).

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[3] Off. for Hum. Rsch. Prots., U.S. Dep't of Health & Hum. Servs., *What is informed consent and when, why, and how must it be obtained?,* Informed Consent FAQs, https://www.hhs.gov/ohrp/regulations-and-policy/guidance/faq/informed-consent/index.html..

[4] *Id.*

[5] Univ. of Iowa, *University of Iowa IRB Standard Operating Procedures (SOP) & Researcher Guide* 38 (2020), https://hso.research.uiowa.edu/sites/hso.research.uiowa.edu/files/forms/2020_SOP_Investigator_Guide_4_Clean_0.pdf.

[6] 45 C.F.R. § 46.111 (2018).

[7] Off. for Hum. Rsch. Prots., *supra* note 4.

As further explained below, beginning in September 2017, upon his arrival at Glenwood, now-former Superintendent Rea embarked on an initiative to conduct experiments on residents of Glenwood and other DHS-run facilities in order to make Glenwood "relevant."[8] Dr. Rea openly discussed with Glenwood staff his plans to conduct such research and briefed senior DHS officials on these plans. Dr. Rea then instigated and directed research related to both physical and behavioral health on Glenwood residents, without their consent and without appropriate safeguards. This exposed residents to harm and violated their constitutional rights to due process, reasonable care and safety, and bodily integrity.

1. Pneumonia, the "Perfect Care Index," and Optimal Hydration

Shortly after he arrived at Glenwood, Dr. Rea began discussing with Glenwood's management staff research from the University of Utah showing a connection between cost and health outcomes for post-surgical patients in hospitals when physicians followed a "value-driven outcomes tool."[9] Part of this tool included a set of variables collectively called "perfect care," which looked at whether key variables met an "evidence-based threshold."[10]

By December 2017, plans were underway to attempt to replicate this framework at Glenwood, focusing on pneumonia, one form of which is a leading cause of death for people with IDD. Glenwood convened a Pneumonia Workgroup (sometimes also called the Perfect Care Workgroup or Perfect Care Index Workgroup) to focus first on reducing mucus build up on the theory that doing so would reduce pneumonia.[11] Glenwood then identified nine individuals with what it documented in meeting minutes as having a "history of frequent pneumonia," current fluid restrictions, and limited mobility, referring to them initially as the "trial group" and subsequently as "Group 1."[12]

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[8] It was Dr. Rea's intention that some of the research would be conducted on Glenwood residents, while other research would be conducted on residents of Woodward Resource Center, the State's mental health institutions, and the Civil Commitment Unit for Sexual Offenders (CCUSO). Our investigation did not examine whether research was in fact conducted on residents of institutions other than Glenwood.

[9] Vivian S. Lee, et al., *Implementation of a Value-Driven Outcomes Program to Identify High Variability in Clinical Costs and Outcomes and Association with Reduced Cost and Improved Quality*, 316 J. of the Am. Med. Ass'n 1061 (2016).

[10] *Id.* at 1063. ("Additionally, the care team selected key quality and outcome variables that were combined into a single binary measure termed *perfect care*. If a continuous variable was chosen as a key variable, the team established an evidence-based threshold (for example, for time receiving mechanical ventilation following coronary artery bypass grafting surgery, <24 hours of time would be considered perfect care).") (emphasis in original).

[11] Dr. Rea was particularly fixated on something he called, according to Glenwood meeting minutes, "mucus-plug pneumonia." However, by the admission of Glenwood's then-Medical Director, "mucus-plug pneumonia" is not a standard or recognized term, mucus plugs and pneumonia are two separate and different events, and there is no known objective way to measure the quantity of mucus secreted by an individual.

[12] At some point later in time, as described below, Glenwood added another group of test subjects and began referring to the test subject groups as "Group 1" and "Group 2." In this Notice, we use the "Group 1" and "Group 2" titles.

Contrary to the recommendation of Glenwood's registered dieticians, Glenwood's medical providers ordered that individuals in Group 1, and subsequently a second group ("Group 2"), receive substantial, uniform increases in fluids that did not reflect consideration for each individual's particular needs.[13] Eight of the nine Group 1 residents were tube-fed and unable to resist increased fluid intake. Even if they were theoretically capable of resisting overhydration, many of the residents also have conditions, such as kidney damage or diabetes, that can inhibit thirst and saturation mechanisms, so their lack of resistance could not be equated with tolerance. Although fluid increases were intended, according to meeting minutes, to continue "as tolerated," there was no written protocol explaining what "tolerated" meant and how to monitor it, nor were nurses and direct care staff instructed to monitor for signs or symptoms of overhydration. Rather, the plan was to continue increasing fluids until there was a sign of a negative impact. The increases in fluids were significant: across Groups 1 and 2 the average increase of hydration was 25% above recommended needs, with the highest increase at 58% above recommended needs.[14] After receiving notice of DOJ's investigation and a later assessment from University of Iowa physicians, the State acknowledged that overhydration was risky to residents and took steps to end it.

a. The Pneumonia Workgroup Was Conducting Research for Which It Did Not Obtain Consent

The overhydration conducted by the Pneumonia Workgroup was a research-driven experimental intervention. The decision to overhydrate the residents was prompted by the theory that overhydration would dilute residents' mucus secretions, making it easier to remove those secretions, and preventing those secretions from causing complications that might contribute to pneumonia.[15] This theory was based on the then-Medical Director's observation that dehydration appeared to have the opposite effect in Glenwood residents: it made mucus secretions thicker and harder to remove. Overhydration is not an established treatment to reduce

[13] The Pneumonia Workgroup also initiated other interventions on the residents, like an enhanced focus on ensuring updated vaccination, increased attention to physical therapy exercises, and additional vigilance on handwashing and other infection control measures. Those interventions in and of themselves are not the focus of this investigation.

[14] Over the lifetime of the Pneumonia Workgroup, Dr. Rea suggested a number of potential additional interventions, also unsupported by evidence, including reducing pneumonia by reducing laxative use and reducing pneumonia by increasing albumin levels. Not all were implemented, though some were. The absence of an IRB meant a corresponding absence of safeguards to prevent unsupported ideas like these from being tested on residents. The evidence available to DOJ suggests that, absent termination of the Pneumonia Workgroup as a result of this investigation, additional interventions were likely.

[15] Some sources told DOJ that overhydration was driven by Dr. Rea, and the then-Medical Director was intimidated into acquiescing to the experiment. The then-Medical Director asserted otherwise, claiming it was his idea. Overhydration is not an established treatment to prevent pneumonia under either scenario.

or prevent pneumonia, and as DHS leadership subsequently acknowledged to DOJ, overhydration was "certainly unconventional."[16]

Procedurally, the work of the Pneumonia Workgroup resembles research, not medical care. According to Glenwood's own policy on research, "any gathering and/or presenting of material, information, or data in any setting outside of normal" interdisciplinary team (IDT) functions is research. The work of the Pneumonia Workgroup was done outside of normal IDT functions. Moreover, if these interventions had been for purposes of medical treatment, one would expect to see them targeted at individuals who needed it, i.e., those with concerning trends related to pneumonia. Instead, however, at least two of the individuals in Group 1 had not experienced pneumonia in the 12 months preceding its inception, and other individuals who had experienced pneumonia more frequently were not included.[17] Finally, one would also expect to see that the interventions would stop, or at least be reassessed, if they were not having the desired effect. We found no evidence this occurred, even though, as discussed below, the occurrence of pneumonia increased in some of the residents and other residents experienced harm.

Contemporaneous documentation supports the conclusion that the purpose and goal of overhydration was research. The Perfect Care "pilot project" was included in a presentation drafted by Dr. Rea about his "objective . . . to create a Glenwood/DHS research program;" the Group 1 residents were identified in Glenwood meeting minutes as the "trial group;" and the minutes show that data was frequently analyzed and reanalyzed to "see if there is a relationship between what we are doing . . . and [the] rate of pneumonia." In fact, according to meeting minutes, the Pneumonia Workgroup expanded the number of test subjects beyond the Group 1 residents to Group 2 in order to get a "reliable number for study purposes," according to a presentation given to Glenwood's monthly quality council meeting. It is clear that Glenwood's goal was to test the hypothesis that overhydration and other interventions would reduce the occurrence of pneumonia.

Because, as explained above, this constituted research, Glenwood was required to obtain the informed consent of the individual participants. Glenwood did not do so when the interventions were implemented in 2018. Instead, about two weeks after DOJ opened the investigation, Glenwood staff, on the orders of Glenwood administrators, called guardians and told them that residents were receiving interventions intended to address their risk of pneumonia. Glenwood administrators then claimed these telephone calls constituted "verbal consent." The

[16] Iowa produced five academic research articles to DOJ in response to a request for all of the research in Glenwood's possession linking hydration and pneumonia. The articles do not support any such link.

[17] Even if the goal of overhydration was connected to individualized need, overhydration differed significantly from routine practice. When a clinician provides a treatment that differs significantly from routine practice, guidance from the University of Iowa provides that "appropriate safeguards [must be] in place to protect the rights and welfare" of the resident. Hum. Subjects Off./IRB, Off. of the Vice President for Rsch., Univ. of Iowa, *Do I Need IRB Review? Is This Human Subjects Research? A Guide for Investigators*, 9-10 (March 18, 2019), https://hso.research.uiowa.edu/human-subjects-research-determination-booklet. No such safeguards were in place, as described *infra*, Section IV.A.1.b.

calls did not seek consent, but rather provided information and assumed consent. No discussion of the risks and benefits of the interventions took place. Glenwood staff were instructed on how to document these conversations by a supervisor. Glenwood staff who conducted these phone calls agreed it was unusual to be seeking so-called "verbal consent" for practices that had been going on for over one year.

Glenwood's then-Medical Director asserted to DOJ that the Pneumonia Workgroup's interventions were not experimental or research-driven, acknowledging that the methodology was so unsound (for example, by implementing so many interventions at once that it would be impossible to identify which, if any, affected pneumonia rates) that it could not have produced any reliable findings, and therefore must not have been for research purposes. Although, as discussed below, he is correct that the research was methodologically flawed, that does not mean it was not research and does not excuse Glenwood's failure to obtain consent. *See infra* note 26.

Similarly, DHS leadership told DOJ that DHS understood the Pneumonia Workgroup's interventions to be a quality improvement initiative, not research. Although there can be circumstances where the distinction between research and quality improvement is unclear, this was not such a case. A key distinction is whether a procedure "known to reduce" a certain outcome is being implemented.[18] Here, the purpose of the work was to test a hypothesis about overhydration and pneumonia. Quite simply, overhydration was not "known to reduce" pneumonia.

By failing to get consent for experimentation, Glenwood violated its residents' due process rights.

b. The Research Conducted by the Pneumonia Workgroup Was Significantly Flawed and Dangerous

When consented-to research is performed, it must be done in a manner that minimizes risk to the participants. *See, e.g.*, 45 C.F.R. § 46.111 (2018) (before IRB approves research, IRB must determine that risks are minimized and subjects are not unnecessarily exposed to risk). The Pneumonia Workgroup's methodology exposed residents to serious harm and risks of harm and failed to comply with virtually all basic safeguards routinely employed in human subjects experimentation. This egregious conduct separately violated residents' due process rights.

No IRB reviewed, let alone approved, the work of the Pneumonia Workgroup. Glenwood's Human Rights Committee did not review, or approve, the work of the Pneumonia Workgroup. Glenwood's Research Committee did not review, or approve, the work of the Pneumonia Workgroup.[19] Due to these lapses, none of the safeguards that would have flowed from IRB review, like assuring true voluntariness, a plan to mitigate and manage risk, and a plan to terminate the research if adverse events occurred, were in place to protect Glenwood residents.

[18] *Id.* at 10.

[19] As of December 2019, Glenwood's Research Committee had not met since August 2016. And the Research Policy was rescinded at some point after August 2018.

Beyond these procedural deficiencies, the Pneumonia Workgroup's study was substantively flawed in several ways. For example, the test subjects included at least two residents who had not experienced pneumonia in the year prior to their inclusion in the study. These residents would have needed to be excluded from analysis of the outcome because it would be virtually impossible to determine whether the interventions were effective in reducing pneumonia. As it pertains to mucus plugs,[20] the flaw was even more severe: only four of the nine individuals had undergone the procedure necessary to diagnose a mucus plug, and none of those four individuals had had one. Similarly, Glenwood did not establish a control group to compare the efficacies of the interventions against, and it implemented all the interventions at once, again making it essentially impossible to conclusively determine whether any of the interventions had any impact on pneumonia.

As Glenwood leadership admitted to DOJ, overhydration is dangerous. Overhydration can impact the nervous, respiratory, cardiovascular, gastrointestinal, hepatic (liver), renal, and skin systems. One side effect of overhydration in particular is hyponatremia (low sodium). Hyponatremia can cause seizures and altered mental status, and it is linked to an increased risk for falling, among many other concerns. A number of medications can cause hyponatremia, which a primary care provider (PCP) would manage by changing medications and/or limiting fluid intake. One third of the Group 1 and Group 2 residents already had hyponatremia before overhydration began. To manage their hyponatremia, some were on fluid restrictions[21] prior to the start of overhydration. More than half saw their sodium levels decrease during the period of time they were subjected to overhydration. Clark Abernathy[22] was a test subject who started receiving overhydration while already experiencing hyponatremia – even while also taking sodium tablets twice a day. His fluids were ultimately increased at least 34% above his recommended needs, and his hyponatremia got progressively worse. Remaining in a state of hyponatremia can shorten a person's life.

For some of the residents, pneumonia increased. For example, in the year prior to his inclusion as a test subject, one resident, Albert Crawford, had two pneumonias. In the 11 months during his inclusion (he died in March 2019), he had six. Another resident, Katherine Cunningham, had one pneumonia in the year before she was included in this trial program, and at least two in the year after, while in the study.

Overhydration caused harm. Ms. Cunningham experienced repeated difficulty breathing, as evidenced by several hospitalizations in 2019. These episodes were suggestive of heart failure, which improved when she was given Lasix, a medication prescribed to treat fluid retention. A primary treatment for heart failure is to reduce liquids to decrease pressure on the lungs and heart. But instead of reducing fluids, the then-Medical Director continued to treat her

[20] A mucus plug is a clog of the airways caused by a buildup of mucus.

[21] For individuals at risk of developing hyponatremia, one method for managing the risk is to reduce fluid intake.

[22] All residents discussed in this Notice are identified using random pseudonyms. We will separately send, under seal, a key containing their true names.

with Lasix – a sign that her respiratory issues were likely linked to excess fluids – while at the same time perplexingly and incorrectly attributing those issues to inflammation. At the time, she was receiving 143% of her recommended daily fluid needs. Another resident, Mr. Crawford, experienced vomiting leading to hospitalization three times in the four months after overhydration began. As with Ms. Cunningham, he received treatment regularly used to manage the effects of fluid overload – his feeding schedule was changed so that it was spread out over a longer period of time, and he was started on Reglan, a medication that forces the stomach to contract, and therefore empty, more frequently – but did not receive the obvious treatment of ending the overhydration.[23]

Despite this evidence, Glenwood's then-Medical Director reported to the Pneumonia Workgroup that fluid increases were not having negative impacts, and asserted the same to DOJ during our investigation. Even without the physical manifestations of harm from hyponatremia, objective lab results showed sodium levels were dropping into unhealthy ranges. But refusing or failing to see and acknowledge these negative outcomes did not erase them. Indeed, current DHS leadership acknowledged that many Glenwood clinicians who should have known these interventions were unusual and dangerous were silent at the time and continue to the present day to resist admitting the Pneumonia Workgroup's work was inappropriate.

DHS leadership at the time of the study did not reveal to State legislators the harms and risk of harm described above. Instead, in a letter to some State legislators responding to questions about Glenwood's unusually high death rate, DHS asserted that these experiments were having a positive impact: From April 2018 to February 2019, DHS told legislators, "[t]he overall percentage of individuals contracting pneumonia due to any cause decreased to 44% (4 out of 9 individuals)." DHS also represented that the rate of "mucus induced pneumonia dropped to zero." This letter was materially misleading.

It did not disclose that incidences of pneumonia for some of the people in Group 1 had actually increased, as described above. Nor did the letter disclose that one of the Group 1 residents had died while being subjected to overhydration. So, naturally, the letter also did not attempt to exclude the overhydration as a contributing factor in his death.

The letter touted the reduction in "mucus induced pneumonia" without disclosing the undisputed fact that "mucus induced pneumonia" is not something capable of being tracked, and that Glenwood was not, in fact, tracking it. Indeed, the documentation the Pneumonia Workgroup reviewed when selecting test subjects shows no evidence that the Workgroup identified or sought residents who had experienced a "mucus induced pneumonia." And, as discussed above, the only test subjects who had undergone the procedure necessary to diagnose a mucus plug did not have mucus plugs – so the starting point was also zero. Finally, highlighting this misinformation about the allegedly promising research was a distraction from the fact that, according to Glenwood's own data at the time of the letter, the average number of individuals

[23] These are also examples of another disturbing pattern: prescribing medication to treat a problem without diagnosing or addressing the source of that problem, or to treat side effects of another medicine without consideration to changing that medicine. *See infra* Section IV.B.1.c.

experiencing an aspiration pneumonia per month per 100 residents had grown by 122% since beginning the experiment, compared to the same amount of time before implementation of the overhydration experiment.

That the letter contained so many misleading statements is a consequence of DHS leadership's abdication of all meaningful oversight of Glenwood. *See infra* Section IV.D. DHS relied entirely on Glenwood to provide the exculpatory and misleading description of the Perfect Care Index, while it ignored concerns raised by a Glenwood staff member in July 2018 that overhydration was falsely premised on research, overhydration could be dangerous – especially the magnitude of overhydration Glenwood's subjects were exposed to (it was), and that a number of test subjects were experiencing pneumonia (they were).

Exposing residents to unnecessary overhydration that increased their risk of harm, and which did cause them harm, then ignoring and concealing the harm, violated residents' constitutional rights.

2. Psychological Experimentation

In addition to conducting research into pneumonia, Dr. Rea instigated a number of related behavioral health experiments. In contrast to the pneumonia experiment described above, there was no pretense here: Dr. Rea openly acknowledged to other leadership at Glenwood and DHS that his goal and purpose were research.

Over the course of his tenure, Dr. Rea pursued many variations of potential psychological research, but, as described in a presentation Dr. Rea made to DHS, they all revolved around a common goal to research "reinforcer pathology" and "impulsivity," which could be applied to drugs, gambling, or sexual behavior. He envisioned conducting this research through a variety of methodologies, including the "Approach Avoidance Task" (AAT),[24] "Delayed Discounting," the "Good Behavior Game," and "ABC" (Attachment Bio-Behavioral Catch-up). In May 2018, with the approval of the DHS Division Administrator for MHDS, and over the objection of senior Glenwood leadership, Dr. Rea directed the purchase of software and equipment to be used for AAT, specifying in an email requesting purchase approval that the software and equipment would be used to apply AAT to "problematic behaviors in Glenwood individuals." Dr. Rea also acquired a set of computer-generated images of nude and clothed children to be used as part of AAT for sexual behavior, which he inexplicably placed on a Glenwood computer although the AAT experiment allegedly was not intended to be used with respect to sexual arousal at Glenwood. DOJ, however, did not identify evidence that the images were shown to Glenwood residents.[25]

[24] AAT involves using a computer joystick to "push" or "pull" away or towards positive and negative pictures.

[25] However, Dr. Rea did direct psychology staff to administer the Socio-Sexual Knowledge and Attitudes Test (SSKAT) to at least three Glenwood residents. This proprietary assessment includes a series of questions and answers, as well as visual illustrations. Staff believed it would be inappropriate, unnecessary, and in some instances potentially harmful to the residents, and for the most part resisted these directions. However, it was partially administered to one resident. Glenwood did not obtain consent before administering the assessment and took no

In the fall of 2018, a small group of Glenwood residents were administered Delayed Discounting questionnaires, both manually and electronically, to measure their abilities to decide between receiving, for example, less money immediately, or more money in a few days. The results of these questionnaires were subsequently sent to collaborating researchers at University of Kansas. The delayed discounting questionnaires did not have a practical purpose related to any specific resident needs. Rather, one of Dr. Rea's apparent goals in administering Delayed Discounting questionnaires first at Glenwood was to determine if there were measurable differences in individuals with impulsivity or intermittent explosive disorder versus those without it and, if so, to consider using delayed discounting as an intervention at Glenwood and other DHS facilities. Another goal may have been to determine whether delayed discounting could be applied to a population of individuals with IDD. Dr. Rea also proposed experimenting with whether administration of a dopamine antagonist such as Haldol impacted sexual arousal and impulsivity.

Glenwood did not obtain consent to administer these surveys, collect data, or use that data, even though consent was indisputably required. With one exception, Glenwood did not even inform the residents' families or guardians that the assessments were happening. The one exception demonstrates that Glenwood was aware that its actions were inappropriate. Glenwood was concerned that one of the residents subjected to the Delayed Discounting questionnaire would share some details of the experience with the resident's parents and that the resident's father, an attorney, might be troubled or concerned. Even then, the family was not informed that data would be collected and sent to the University of Kansas. And, as with the Pneumonia Workgroup, there was no review of the Delayed Discounting research by an IRB, Glenwood's Research Committee, or Glenwood's Human Rights Committee.[26] Further, as with the overhydration experimentation, *see supra* Section IV.A.1.a, failure to obtain consent for these psychological experiments violated residents' due process rights.

This violation occurred without meaningful oversight by DHS, although DHS was on notice of GRC's research activities. A Glenwood manager had told the DHS Director in July 2018 that Dr. Rea was directing research projects that were based on "completely debunked" and

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follow up actions based on the results of the assessment. It is inappropriate to conduct an assessment when there is no treatment purpose for the assessment, and even more inappropriate to do so when the assessment may be risky for the assessed individual (as Glenwood's clinicians believed it was for these residents).

[26] Some Glenwood staff told DOJ that they deferred to Dr. Rea for instructions on when informed consent was necessary, in light of his experience as a published researcher. However, Glenwood's research policy was clear on the need for consent. But even assuming this deference was reasonable, Dr. Rea knew exactly what needed to be done, and did not do it. When Dr. Rea conducted research on sexual arousal that was published in 2003, "consent was obtained from the participant (an advocate was available to ensure that he understood what he was consenting to), his guardian, his treatment team, the facility's behavior review and human rights committee, and the Advisory Committee on Human Experimentation. The participant was told that he could withdraw from the study at any time." Jerry Rea et al., *Covert Sensitization: A Generalization Analysis in the Laboratory and Natural Environment Through the Use of a Portable-Penile Plethysmograph*, 4 The Behav. Analyst Today 192, 194 (2003). Dr. Rea was also aware of the need for IRB approval of research because he submitted a proposal to the University of Kansas IRB for AAT research to be done in collaboration with Kansas-based researchers. And, in connection with that proposed research, he exchanged numerous drafts of a script to be used to obtain informed consent.

"inaccurate" premises, and that Dr. Rea was unable to articulate how "Glenwood residents will be involved or benefited" by the research. But DHS did not follow up. Further, in addition to obtaining the Division Administrator's approval to purchase software and related equipment, Dr. Rea sought DHS leadership's approval for the entirety of his research vision in an August 2018 meeting. According to contemporaneous reports from Dr. Rea to Glenwood leadership, and to staff who worked with Dr. Rea on the proposal, he received a "green light" and a positive reception. According to what the then-DHS leadership told DOJ, however, the proposal was flatly rejected. Regardless, it is clear that Dr. Rea engaged in research activities after this meeting.

In early 2019, DHS was asked by members of the Iowa legislature whether research was occurring at Glenwood. DHS reported to the legislature that the answer was no, but did not check before making that report. Nor did DHS follow up several months later when, in August 2019, Dr. Rea sought and obtained DHS permission to travel to Kansas to meet with his proposed research collaborators on the very research projects that had reportedly been vetoed. This prompted no follow-up inquiry by DHS.

Subjecting residents to psychological experimentation without obtaining consent violated their constitutional rights.

B. Glenwood's Inadequate Medical and Psychological Care Violates Residents' Rights

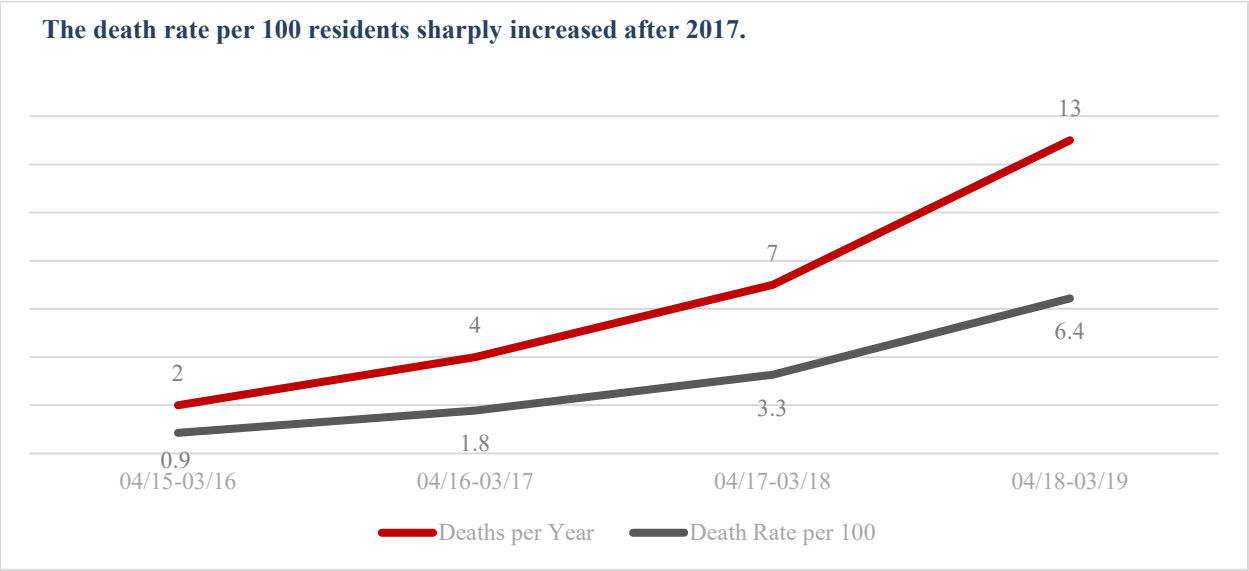
1. Physical Health Care

State institutions must protect their residents from unreasonable risk of harm by providing adequate medical care. Failure to act when action is obviously needed is deliberate indifference. *Hope v. Pelzer*, 536 U.S. 730, 737-38 (2002) ("We may infer the existence of this subjective state of mind from the fact that the risk of harm is obvious."); *Schaub v. VonWald*, 638 F.3d 905, 916 (8th Cir. 2011) ("[T]he requisite knowledge of a substantial risk may be inferred from circumstantial evidence, or from the very fact that the risk was obvious."); *see also Lanman v. Hinson*, 529 F.3d 673, 684 (6th Cir. 2008) (requiring a showing that staff "knew of and disregarded an excessive risk to [plaintiff's] health or safety").

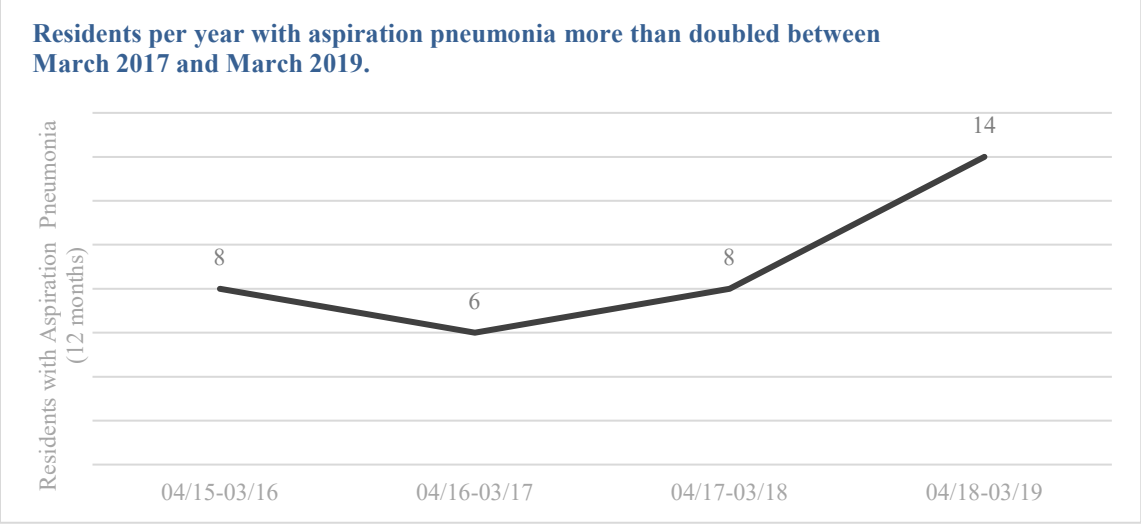
As to health care in particular, "when the need for treatment is obvious, medical care which is so cursory as to amount to no treatment at all may amount to deliberate indifference." *Mandel v. Doe*, 888 F.2d 783, 789 (8th Cir. 1989); *see also Smith v. Jenkins*, 919 F.2d 90, 93 (8th Cir. 1990) ("[T]he district court erred as a matter of law in ruling that mere proof of medical care by a doctor consisting of diagnosis only sufficed to disprove deliberate indifference."); *Coppage v. Mann*, 906 F. Supp. 1025, 1041 (E.D. Va. 1995) ("an unusually long delay between the emergence of a serious medical need and treatment of that need may provide a reasonable basis for an inference of deliberate indifference"). On the other hand, if care is provided, it is nonetheless constitutionally deficient if it is "so inappropriate as to evidence intentional mistreatment or a refusal to provide essential care." *Dulany v. Carnahan*, 132 F.3d 1234, 1241 (8th Cir. 1997); *see also Meuir v. Green Cty. Jail Employees*, 487 F.3d 1115, 1118 (8th Cir. 2007) (requiring a showing that facility staff administered inadequate treatment).

a. Glenwood is Deliberately Indifferent to the Physical Health Needs of Residents

The death rate at Glenwood sharply increased after 2017, even as Glenwood's population shrank by more than 10%.



Five bowel obstructions occurred and there were 87 skin breakdowns from April 2018-March 2019, compared to only three bowel obstructions and 40 skin breakdowns in the period April 2016-March 2017. Further, aspiration pneumonia also sharply increased.



These indicators suggest, and our investigation confirmed, significant breakdowns in the quality of physical health care provided at Glenwood, exposing residents to harm and serious risks of harm. Iowa has been deliberately indifferent to those breakdowns and the risks they pose.

Glenwood frequently leaves residents at serious risk of harm or death by ignoring changes in condition outright, or by adopting a clinically unjustified "wait and see" approach. In

a facility like Glenwood, where residents have a number of complex medical conditions, often have limited verbal communication skills, and take a number of medications with significant side effects and drug-drug interactions, generally accepted standards of practice require medical providers to closely monitor, assess, and respond to changes in condition like changes in breathing, changes in mental status, behavioral changes, or others. Although the appropriate intervention might vary depending on the type of change in condition and its severity, two things are constant: changes in condition require a timely assessment by a PCP, and they require timely and clinically appropriate follow-up.[27] Glenwood's medical providers failed to do so, and failed to take corrective actions in response to this pattern of failures.

For example, resident Benjamin Drisden complained of abdominal pain in the early morning hours of August 18, 2018, stating "I can't do it, it hurt [*sic*] so bad," and then asked to go to the hospital. The resident had PraderWilli syndrome, a symptom of which is a high pain threshold. Consequently, when an individual with PraderWilli syndrome complains of pain, that is an unusually significant complaint.[28] Also, he was designated by Glenwood as at risk for bowel obstructions, and only two months earlier, following abdominal surgery, had experienced multiple complications resulting in an extended stay in the hospital. He remained in significant pain until later in the day when, after having explosive diarrhea and stating he was going to vomit and pass out, he was sent to the hospital by nonemergency transport. The pain was from a bowel obstruction that then ruptured and killed him. Glenwood's unresponsiveness to his initial complaint gave him virtually no chance of survival.

As another example, on August 27, 2018, Albert Crawford's blood pressure was reported as 63/27, a dangerously low level. He was also experiencing low oxygen saturation, even with a nasal oxygen supply, and a decreased pulse – additional independent signs of a change in condition requiring assessment and response. But the PCP did not send him to the emergency room, and did not perform an in-person assessment. Instead, the PCP directed staff to invert him such that his feet were above his head. Mr. Crawford was fed via a tube and was at high risk for

[27] As applied to lab results specifically, there must be a process with deadlines for reviewing labs, acknowledging abnormal results and identifying a follow-up plan (which may include specialist consultations), and documenting each of the above steps. In March 2020, Glenwood's PCPs told DOJ that there is a protocol in place for documenting that lab results arrived, were reviewed by a PCP, and that the PCP identified abnormalities (if any) and developed a plan to address them. We found evidence that this protocol was routinely not followed, leading to many abnormal lab results that were not appropriately followed up on. Iowa acknowledged that follow-up on labs was an area requiring improvement and began to implement corrective actions while DOJ's investigation was ongoing. Those corrective actions were, however, inappropriately narrow.

[28] We saw an alarming trend of failure to appropriately assess pain. Another example relates to Felix Undergrove. A PCP did not act on abnormal lab values for over one week. In that time, the resident was likely in pain, as evidenced by repeated reports of agitation. An assessment by the PCP on Christmas Day 2017 found inflammation and drainage around his feeding tube – the equivalent of the skin being broken down by intestinal enzymes – which is typically quite painful, but the assessment incredibly documented no pain. He received no treatment for pain, and instead was given psychotropic medication to suppress the agitation.

aspirating[29] (that is, inhaling food, liquid, vomit, or other matter into the lungs). His risk of aspiration was managed in part by ensuring that his head was always elevated and that he remained upright during, and for 30 minutes after, taking medication. Nevertheless, the PCP also directed staff to continue his tube feeding while he was inverted. These orders are gross departures from generally accepted professional standards of care, and we have identified no plausible justification for them. But, as a consequence, Mr. Crawford remained in an inverted position overnight for hours while being tube fed. He was hospitalized the next day, with aspiration pneumonia.[30]

Glenwood leadership told us that the expectation is that PCPs should respond to concerns raised by all staff, conduct in-person assessments sooner and faster than current practice, and stop relying on "baseline" findings, because such findings can mask or routinize a slow decline. In an assessment conducted after DOJ began its investigation, University of Iowa Health Care recommended to Glenwood that "any acute change in condition that poses a risk for injury or death be evaluated immediately with transfer to an outside facility based on medical provider or nursing concerns." Indeed, even in our interviews of the PCPs themselves they acknowledged an understanding of the importance of timely review of lab results and physical assessments, for example. But the events described here reveal a failure to translate that understanding into constitutionally compliant care. That same pattern was clear during observations of daily medical staff meetings in March 2020.

Iowa has been deliberately indifferent to the risks these practices create for Glenwood residents. The concerning trends described above were never cause for concern to Glenwood – not even in retrospect – because, according to Glenwood's then-Medical Director, sometimes deaths happen in clusters. When DHS was confronted by media inquiries about the increase in deaths at Glenwood in the first part of 2019, DHS dismissed the trend by pointing to the age of the residents, and took no steps to determine if the increase in deaths was linked to clinical deficiencies. Similarly, when current and former Glenwood staff contacted DHS to express concerns about the quality of Glenwood's medical care, DHS leadership brushed them aside as "disgruntled" employees, and made no attempt to investigate whether their concerns had merit. *See also infra* Section IV.D.

Such an inquiry would have been straightforward because much of the work was already done: mortality reviews conducted by an external organization repeatedly found that Glenwood's management of acute care needs was an area of concern in need of improvement. In the 19 deaths between June 23, 2018 and December 12, 2019 reviewed by this external organization, the need to address timely acute care was identified in at least eight cases. In fact, in one May 2019 review, the external organization recommended the significant and drastic step

[29] Aspiration is one of the four health issues commonly linked to preventable deaths in individuals with intellectual disabilities.

[30] This episode was possibly triggered when his prescription for Zanaflex, a muscle relaxant with sedating effects including shortness of breath and a lower heartbeat, was more than doubled from 6mg/day to 16 mg/day, with more than half of that coming in a single dose at bedtime. This recommendation from a consulting physician was implemented by the Glenwood PCP without any documented consideration of potential side effects.

of a root cause analysis "to explore the possible reasons for delays in hospital transfers." By the last one, written on December 30, 2019, this external organization was stressing the need for "GRC administration" to examine the decision process about transferring residents to the hospital. But, as described below, *see infra* Section IV.C.2.a, these recommendations and warnings were largely ignored.

In fact, Glenwood's own mortality review process was structured in a way to make sure as few people as possible were even aware of these external recommendations. Even when prompted by the DHS Central Office to identify follow-up actions in light of these recurring recommendations, Glenwood dismissed them or offered vague assurances they had been addressed – assurances DHS did not probe or verify.

By failing to appropriately respond to residents' changes in health status, and failing to respond to this pattern of failures, the State violates Glenwood residents' due process rights.

b. Glenwood Routinely Fails to Provide Appropriate Integrated, Interdisciplinary Physical Health Care

Glenwood residents, like others with IDD, have complex, inter-related medical needs. Generally accepted professional standards require coordination between physicians across multiple specialties (e.g. psychiatrists and neurologists), as well as among the team of Glenwood clinical and non-clinical staff, to manage those needs. Glenwood, however, fails to perform this necessary coordination. As a result, residents do not receive appropriate treatment, with sometimes fatal consequences.

Appropriate physical health care requires coordination and effective information sharing between medical staff and direct care staff. This is absent at Glenwood, as is clear when examining the management of epilepsy. In addition to basic training on epilepsy and the different general types of seizures, direct care staff and nurses should receive, for every person they support who experiences seizures, person-specific training including what a seizure looks like for each resident. But that does not happen at Glenwood. Staff do not receive individualized training on seizure identification and instead report anything that might have been a seizure to PCPs as an "apparent episode," which PCPs assume without investigation were truly seizures. *See also supra* Section IV.A.1.b (failure to instruct direct care staff to be alert to signs and symptoms of overhydration).

In addition, because staff do not know how to identify a seizure, they cannot provide clinically necessary information to PCPs about the seizures, and PCPs do not necessarily follow up to make a record of whether any given "apparent episode" was or was not truly a seizure. As a result, consultations with neurologists are ineffective, with recommendations to maintain current treatment plans even when they are clearly inappropriate, as the interim Medical Director acknowledged. For instance, without an accurate description of the type of seizures a resident experiences, the neurologist may prescribe a medication ill-suited for that kind of seizure, potentially worsening the seizures, as happened with Maxwell Smyth. He was on five seizure medications, including one that was inappropriate for his seizure condition.

Glenwood also does not ensure that information flows between professionals in different departments. In fact, Glenwood's system for sharing information between various departments is essentially broken. We observed several daily clinical staff meetings and observed a recitation of various changes in condition (often referred to at Glenwood as "triggers") without appropriate follow-up discussion or action steps. As recently as May 2020, a member of Glenwood's clinical staff confirmed to DOJ that reports of changes of conditions were essentially done by rote and did not generate appropriate follow-up. As that same person told DOJ, "the left hand doesn't know what the right hand's doing and [there is] a lack of curiosity about the person's whole care." This is a failure of what a team of external consultants brought in by the State to assess physical health care at Glenwood acknowledges is a critical component of care.

For instance, lack of clear responsibility among medical, psychiatry, and neurology for medication decisions leads to treatment inertia or inappropriate treatment changes. We saw a number of examples where psychiatry and neurology fail to collaborate or accept primary responsibility for medications prescribed to treat seizures and/or psychiatric symptoms (so-called "dual use medications"). As the State's Expert[31] concluded, "[d]ocumented coordination between psychiatry & neurology is needed to assure appropriate clinical treatment."[32]

One example is Louis Alexander, who is prescribed Depakote, though there is no justification for the continued use of this medication. The symptoms of Depakote toxicity place the resident at increased risk of aspiration pneumonia, and, indeed, he had aspiration pneumonia in early 2020. He continued on this medication because no one doctor took responsibility for it: his PCP documented in April 2019 that he received it for psychiatric reasons, but a few days later the psychiatrist took Depakote off of the list of psychiatric medications and noted the Depakote would be monitored by neurology instead. Similarly, Elena Murray, who died in late 2019 when she was found unresponsive in her bed, had Rett syndrome, a genetic syndrome placing her at increased risk of sudden death due to cardiac abnormalities. Her annual Individual Support Plan (ISP) noted that she should receive annual cardiac testing and not take any medications with a risk of prolonging her QT interval. And yet she was taking one such drug, Lexapro, increasing the risk of prolonging the interval and potentially leading to possible sudden death. We found no evidence that Glenwood's clinicians considered changing the Lexapro to a different antidepressant.

Another tragic example of the harm that occurs when clinicians do not work together according to standards of care relates to Sebastian Vern. He had cervical spine (i.e., the portion of the spine in the neck) surgery in March 2019. His interdisciplinary team met one week before the surgery to discuss a concern that he might not react well to wearing a neck brace. The plan – to wait and see how things unfolded – was inappropriate. Glenwood's psychology department

[31] In December 2019, the State retained an expert consultant (State's Expert) to, among other tasks, "[e]valuate [Glenwood's] services for compliance to generally accepted practice standards," "[i]dentify areas of needed improvement," and "[d]evelop an improvement plan to address areas that need improvement." In May 2020, the State's Expert produced a document entitled "Glenwood Resource Center – Preliminary Report," which we cite as "State's Expert Report," and a separate document entitled "Recommendations for Remediation."

[32] State's Expert Report at 9.

should have been involved to identify strategies to prepare and acclimate him to the neck brace. After he came out of surgery he was not offered a neck brace, became agitated and aggressive, was found asleep with his neck directly on a bed rail, experienced post-surgical complications, and died.

As a final example of Glenwood's failure to provide appropriate integrated, interdisciplinary care, Glenwood's response to resident falls, particularly with respect to evaluating for potential head injuries, is deficient. Isaac Percy fell on the morning of August 12, 2019 and, although staff slowed his fall, he fell on his left hip. Although he had osteopenia, and appeared to be unable to put weight on his left side intermittently after the fall, he was not x-rayed until August 14, 2019. The x-ray showed a femur fracture, for which he required surgery. The delay in assessing the cause of his pain was so distressing that a group of his direct care staff filed a complaint on his behalf with Glenwood's Human Rights Committee. Staff who complained on his behalf were reprimanded by Dr. Rea for questioning decisions by the PCP and one staff member was specifically told he should not raise concerns about the quality of medical care because it was "disrupt[ive]" to staff.

The nursing department plays a key role in coordinating and prioritizing care across various disciplines. But a key opportunity to play that vital role is squandered every month. There is a monthly meeting about every resident to review data and information from the prior month to identify and respond to emerging trends. The nursing department should be directly reviewing records to identify minor incidents that may indicate a trend and may otherwise go unnoticed. However, nurses simply cut and paste from other collections of data, resulting in, at best, a superficial overview of the individual's month, which is a substantial departure from generally accepted standards. Consequently, nurses do not reliably identify appropriate information, such as decreased food intake by an individual who, it turned out, had advanced cancer. Moreover, these meetings are typically held so late in the following month that the data reviewed is stale, and opportunities to make adjustments to respond to trends have been lost.

In this context, the State's failure to appropriately coordinate care among clinical departments and direct care staff despite the known risk of harm that failure poses to residents violates Glenwood residents' due process rights.

c. Glenwood Does Not Appropriately Prescribe Medications

Generally accepted professional standards limit prescriptions of medicines to the minimum effective dose needed, and only if the benefits of the medication outweigh associated risks. Glenwood substantially departs from generally accepted professional standards in prescribing medications in a number of respects. For example, at least four Glenwood residents with gastrointestinal problems were prescribed osteoporosis medications from a family of drugs that worsens gastrointestinal problems, instead of medications without that side effect. This contraindication is contained in a "black box warning" for these osteoporosis drugs, meaning the drug should be avoided, or, if there is no possible alternative, the prescriber should discuss the risks with the resident (and/or their guardian), obtain consent to prescribe only if the benefits outweigh the risks, and identify additional monitoring needed to watch for negative outcomes.

But although Glenwood's pharmacists generated reports that identified these black box warnings,[33] we found no evidence that Glenwood's PCPs responded to those warnings or discussed the risks and benefits with, and obtained informed consent from, residents and/or their guardians for these medications or for others where consent would be expected. One resident, Lincoln O'Brian, is on a seizure medication that is inappropriate for his particular syndrome – Angelman syndrome – because it can make his seizures worse, but there was no acknowledgment of this problem or an attempt to change the medication. Another resident, before she died, was on six seizure medications, nearly all of which were very sedating, and was noted to be "drowsy" when examined by the neurologist. That she ever got to the point of being on so many seizure medications simultaneously raises significant questions about how prescription decisions are made and overseen.

Another variation of problematic medication management is that medications may be prescribed to treat symptoms, without diagnosing or addressing the underlying cause of those symptoms. For instance, Samantha Willis was also inappropriately placed on an antipsychotic medication while simultaneously on Keppra, a seizure medication that can cause depression. She should have been trialed on a different seizure medication to see if Keppra was causing the psychiatric symptoms before adding a psychiatric medication, but we found no evidence this happened, or documentation justifying why it did not. Glenwood's interim Medical Director admitted to DOJ that a lot of Glenwood residents were prescribed psychotropic medication without a clear appropriate diagnosis. And the use of psychotropic medication at Glenwood is "unusually high," according to the State's Expert.[34]

All of the above problems with prescriptions suggest that medication orders are not appropriately individualized. That is especially clear in Glenwood's procedures for prescribing Diastat, a medication administered to people experiencing prolonged and/or cluster seizures. Standing orders for Diastat for individual residents are appropriate, but must be tailored to individualized needs, identifying the type of seizure that Diastat should be used for. Diastat orders should also require immediate notification to the PCP that Diastat was given and clarify that (typically) Diastat should not be given for breakthrough seizures – i.e., a seizure that comes after a long seizure-free period. Glenwood's Diastat orders are not individualized and are not clinically appropriate. Instead, they are virtually identical person-to-person, except for adjustment in dosing.[35]

[33] Glenwood's Pharmacy Director, who was relatively new to the position, acknowledged to DOJ that she received no training on providing pharmacy services in a facility like Glenwood when she began, and described limited involvement in clinical decision-making. This may be one of several reasons why, even when the pharmacy appropriately identifies potential side effects, appropriate actions are not taken.

[34] State's Expert Report at 21.

[35] Glenwood's PCPs told DOJ about what they portrayed as an in-depth effort to collaborate with consulting neurologists in the second half of 2019 to analyze various factors to individualize the Diastat orders. But the outcome of this process, the Diastat orders themselves, are inappropriate, as described above.

These failures to appropriately prescribe and manage medications are because Glenwood's medication decisions and information are heavily and inappropriately siloed. For example, even when Glenwood's pharmacy appropriately includes side effect warnings in quarterly and annual reviews, we did not find evidence that these warnings were reviewed, considered, and acted on by PCPs as a matter of practice. Further, direct care staff are not informed when medications are changed, and the psychiatrist and PCPs do not have established procedures for communicating about potential side effects, or consulting about potential medical causes of psychological problems (or vice versa).

In the same vein, monitoring for potential side effects is completed by nursing, but there is no evidence PCPs regularly review and act on the findings, even when there is a finding of significance requiring PCP review. The State's Expert concluded, and DOJ agrees, that psychiatry consultations need to be better integrated with, and based on clear data from, the psychology department.

Although Glenwood recently re-started a committee to examine the use of multiple psychiatric medications for individuals, no analogous review exists for neurological medications. And this committee generates aggregate data that masks a lack of progress on reducing polypharmacy on an individual level. In these and other ways described in this Notice, Glenwood places its residents in harm's way by poorly managing prescriptions, in violation of their due process rights.

d. Glenwood Does Not Safely Dispense or Administer Medication

Medication variances (i.e., discrepancies in dispensing or administering medications) can cause significant harm. Individuals who receive extra doses of prescribed medications, who miss doses of prescribed medications, or who receive the wrong medications all face potential risks, including side effects, allergic reactions, or dangerous drug interactions. For this reason, generally accepted professional standards require institutions like Glenwood to implement reliable safety mechanisms to guard against variances, and to investigate variances to take corrective and preventative actions. Glenwood substantially departs from these standards.

According to Glenwood's records, the medication error rate in March 2020 was 6.2%, exceeding even the facility's self-determined benchmark by more than 200%.[36] Although Glenwood did not calculate an error rate for April 2020, there were more variances in April than there were in March.

Many of the variances are significant. For example, in March and April 2019 Nathan Tarnley received a double dose of Haldol for 27 days. The likely side effects of this overdose, including an increase in falls so extreme that he began to use a wheelchair and declined in his ability to communicate, required a referral to a movement disorder clinic. In August 2019, October 2019, and November 2019, at least one person per month received another person's medication, including, disturbingly, in October 2019, when Maury Ardenton received someone

[36] As discussed below, these rates understate the true frequency of medication errors.

else's phenobarbital, a barbiturate drug to which he is allergic. In May 2019, an after-the-fact audit from the pharmacy department determined that there were 36 instances in a 49-day period where this resident, who had previously been hospitalized with a bowel obstruction, did not receive his prescribed laxatives. In December 2019, the Pharmacy Department's after-the-fact audits identified similar failures to administer laxatives or other medications affecting at least 22 different residents. These audits continue to identify long-lasting variances in 2020.

Glenwood's records likely undercount the true number of variances, by significant magnitudes. First, as discussed below, Glenwood's limited review of reported medication variances reveals that medication administration records sometimes wrongly represent that medications were administered when they were not.[37] Second, Glenwood counts multiple variances as a single error. For example, the May 2019 incident of not administering 36 doses of a laxative was counted as a single variance. It is likely that the monthly number of medication variances at Glenwood is in fact in the triple digits each month, if not higher.

Glenwood's investigations of these variances are inadequate. The Medication Variance Review Committee attempts to review documentation related to each variance and determine its "root cause," but does so without direct knowledge of the circumstances surrounding the variance. The Committee does not, but should, conduct observations and interviews to help understand the potential causes of a variance. For instance, in the Committee meeting we observed, the Committee theorized that staff might not be dispensing liquid laxatives because liquid medications are stored separately and might be difficult to find. But the Committee had no evidence suggesting that this is the most plausible root cause, and the Committee's conclusion did not address the fact that staff were filling out medication administration records to wrongly assert that they had been administering these medications.

The Committee's classification of the severity of variances is also inappropriate. A remarkable example is the Haldol variance described above, which Glenwood downgraded to a category wrongly indicating that the variance caused no harm, even though it likely caused Mr. Tarnley a large number of falls and a hampered ability to communicate. Separately, we received numerous reports that medication errors are likely attributable to low staffing levels, and allegations that attempts to gather data to verify and address such reports were met with hostility by Glenwood's then-leaders.

In February 2020, there were reasonable grounds for suspicion that a significant change in a resident's mental status and physical strength might have been caused by a medication variance. Very early in the morning on February 5, Linda Quentin was unable to walk, and according to the nurse who assessed her, "looked like an infant lying on the floor." She was covered in urine and crying out for help. After trying three times to arrange a non-emergent transport to the hospital, the nurse sought and obtained permission from the on-call PCP to send

[37] Only the inconsistencies captured through after-the-fact pharmacy audits are being counted. This is a dangerous practice.

her to the hospital via ambulance.[38] Although Glenwood staff immediately wondered if a medication error had occurred,[39] this was apparently not relayed to the on-call PCP or to the hospital.[40] Indeed, supervisors at Glenwood were aware of the possibility there had been a medication variance, but did not investigate further at the time in part because no variance had been reported. This assumption was problematic, because, as Glenwood's psychiatrist noted, "it is important to have prompt reporting. Had the hospital been aware of a possible medication error, they could have done a blood test." She was discharged back to Glenwood within a few hours, still very weak and unable to walk.[41]

Multiple staff members reported effectively the same thing: at a subsequent team meeting about this incident the then-Medical Director was not willing to have an open discussion, and exhibited his "typical" dismissiveness of staff concerns. Glenwood's Quality Management ("QM") Department subsequently completed an investigation and identified "no systemic concerns," and Glenwood's Incident Management Committee subsequently reviewed the investigation and its conclusion, and found no fault with the investigation. In fact, there were multiple systemic concerns, as outlined above.

Glenwood's medication dispensing and administration systems place residents at serious risk of harm, in violation of their due process rights.

e. Glenwood Fails To Maintain Adequate Records

"A necessary component of minimally adequate medical care is maintenance of complete and accurate medical records." *Ginest v. Bd. of Cnty Comm'rs of Carbon Cnty*, 333 F. Supp. 2d 1190, 1200 (D. Wyo. 2004) (citing *Coleman v. Wilson*, 912 F. Supp. 1282, 1314 (E.D. Cal. 1995)). Failure "to take reasonable steps that will aid in obtaining necessary medical information" from records, including failing to implement a system for doing so, can be deliberate indifference. *Ramirez v. Ferguson*, No. 08-cv-5038, 2011 WL 1157997, at *20 (W.D. Ark. Mar. 29, 2011). Glenwood substantially deviated from this requirement.

Glenwood's record-keeping system is neither complete nor accurate. Glenwood leadership admitted they are "not satisfied with the medical record," and there are many gaps. Glenwood's Pharmacy Department maintains a spreadsheet to track psychiatric and seizure medications replete with inaccuracies that ranged from the inclusion of medications that are neither for psychiatry nor seizures to missing dose changes.

Similarly, DOJ identified a number of circumstances where PCP or nursing documentation was facially implausible or incomplete, suggesting that staff may be documenting

[38] It is inappropriate for nurses to need to seek permission to call 911.

[39] Given the sudden onset of her symptoms, a medication error would appropriately be first on a list of likely causes.

[40] *See supra* Section IV.B.1.b, describing breakdowns in information sharing at Glenwood.

[41] It was inappropriate to accept her back to Glenwood while still symptomatic and without an identified cause for her symptoms.

they took certain actions which they in fact did not. For example, nurses frequently document certain ear and eye assessments that require specific equipment and specialized training to complete, without commenting narratively on why those assessments were completed. These assessments are unusual for nurses in any setting, but notably more unusual here, given the general absence of targeted nursing training at Glenwood.

Separately, nurses should be checking for something called residuals in tube-fed residents: the presence of residuals is a signal of a digestive problem and may increase risk for other issues. However, nurses do not appear to be documenting those checks correctly. For one resident, his residuals were consistently documented as zero, even within hours of his vomiting, which is extremely unlikely because the absence of residuals would indicate the absence of stomach contents to vomit. Medication side effect monitoring documentation was also facially incomplete. For instance, the monitoring for one individual noted no abnormalities, but the neurologist noted two abnormalities. And the individual was on a psychotropic medication that is among the drugs that most frequently causes the abnormalities found by the neurologist.

In addition, the record-keeping system permits records to be overwritten in a way that makes it difficult to determine that a change was made, let alone what the change was. This makes record manipulation possible. In August 2019, a supervisor instructed a direct care worker to rewrite the narrative of an incident that occurred while off campus with a resident. The first entry described the resident attacking staff; the rewritten version merely stated the resident exhibited "dangerous behavior." This occurred a few months after Glenwood was fined by the Iowa Occupational Safety and Health Administration for failing to protect staff from resident aggression, and in the same month that Glenwood received a follow-up warning. *See infra* Section IV.D. Separately, a nurse who conducted an assessment following a statement by a resident that she has been sexually abused was directed by her supervisor to change the documentation so that the allegation was falsely identified as physical abuse instead of sexual abuse. Another nurse reported that Glenwood leadership routinely instructed nurses to exclude information that the victim alleged sexual abuse, contrary to standard nursing assessment practices.

Finally, Glenwood shares records with outside regulators, such as the Iowa Board of Medicine and the Medical Examiner, that omit critical information. In particular, records provided to the Board of Medicine and Medical Examiner do not include the time and date that a particular record entry was created, but instead only include the date and time about which the entry pertains.

Glenwood lacks the complete and accurate medical records system that is a necessary component of constitutionally adequate physical health care.

f. Glenwood's Medical and Nursing Departments Are Structurally Deficient

Numerous underlying deficiencies contribute to Glenwood's failure to provide constitutionally adequate physical health care. First, Glenwood's physical health care staff are insufficiently trained to provide the necessary coordinated and integrated care. Three of the four

PCPs working at Glenwood at the time DOJ opened its investigation had no prior experience working with individuals with IDD. In fact, they had no prior work experience as licensed PCPs. Further, they receive no budget or time off for continuing education, and their training during orientation was limited. Their primary source of training was the then-Medical Director, whose clinical judgment is inadequate. Similarly, the infection control/wound care nurse received no specialized education or training in either infection control or wound care, and, by her own description, received only "spotty" on-the-job training from her predecessor. Leadership in the Nursing Department confirmed that nurses generally are inadequately trained. In fact, in 2018, the facility as a whole significantly reduced the training it provided to new staff during orientation.

In particular, a concerning knowledge gap relates to recognizing and assessing pain in Glenwood residents. For example, during one medical staff meeting we observed, a PCP noted that it was difficult to evaluate pain in one resident because of that resident's dementia, but there are indeed pain assessment techniques specifically for individuals with dementia. When Wilbur Kenny was experiencing respiratory distress in November 2019, he was also displaying potential signs of pain, but when the PCP finally conducted an assessment, he claimed that he could not assess for pain because the individual did not communicate verbally. But this person was able to communicate by vocal noises, facial expressions, and nodding or shaking his head, and the PCP should have assessed for pain based on this communication.

Another knowledge gap relates to skin care and decubitus ulcers. The existence of decubitus ulcers, colloquially known as bedsores, pressure sores, or pressure ulcers, is an indicator of the overall quality of care provided in a facility. Although Nursing Department leadership asserted to DOJ that Glenwood residents experience decubitus ulcers infrequently, Glenwood subsequently produced the charts of 11 residents who had experienced a decubitus ulcer in 2019 alone. One of those residents, Mr. Kenny, routinely developed ulcers on his buttocks in 2018 and 2019. Despite the recurring wound, it appears that he did not receive a PCP's assessment for it – in fact, he had the wound on the same day as his annual physical, but the PCP did not even mention it – and he was never referred to a specialist. When he was sent to the hospital shortly before his death, he had an ulcer that Glenwood had staged[42] as Stage I, although it was in fact a Stage II.

Second, staff operate in the absence of policies or procedures that would guide their clinical judgment. For instance, although Glenwood's policy requires a "timely" response to changes in condition, the policy does not define "timely," deferring instead to individual clinical judgment. As demonstrated above, that judgment is too frequently incorrect. Further, leadership in the Nursing Department was, by and large, unable to identify or describe Nursing Department policies and procedures.

Third, the then-Medical Director, though nominally a member of various Glenwood leadership and quality committees, did not attend those committees' meetings on a regular basis.

[42] Staging of a decubitus ulcer refers to diagnosing its severity. The higher the stage, out of a total of four, the more severe the ulcer is.

This cut off opportunities for the Medical Department to be subjected to facility-wide quality assurance and quality improvement efforts, for instance, and also cut off the Medical Department's ability to know about and provide a clinical perspective on the impact of changes elsewhere in the facility. The then-Medical Director attributed his absence to extreme turnover of PCPs within the medical department, and the need to prioritize onboarding new PCPs and providing direct clinical care to the residents on his caseload. And the then-Medical Director shared the same size caseloads as the other PCPs. This was problematic for two reasons. First, it left him with insufficient time to carry out his responsibilities as head of the department, which are necessary to ensuring proper operations. Second, he was providing clinical care without regular assessments of his own clinical competence.[43]

Finally, there is an absence of meaningful quality assurance, quality improvement, and oversight of clinical care. Although the PCPs engage in a process nominally called "peer review," that process focuses on checking that documentation is complete and compliant with deadlines. It is neither intended to be, nor is it used as, an opportunity for review of the quality of clinical care. And this pro forma process is limited to the work of PCPs, excluding psychiatric and neurological services. Similarly, peer review in the Nursing Department appears limited to auditing for documentation requirements rather than quality.

DHS's failure to identify and demand a correction to the many deficiencies in physical health care at Glenwood stemmed in part from a vacuum of physical health expertise within the Central Office. DHS was presented with concerns or complaints about inadequate physical health care – especially related to an increase in deaths – on multiple occasions. Even if DHS investigated such issues, which it frequently did not do, there was no one within the Central Office with medical or nursing knowledge, and no external equivalent, that DHS could rely on to provide insight. *See infra* Section IV.D. Instead, DHS had to rely on the very same people – Glenwood staff – whose actions were at issue. As discussed below, *see infra* Section IV.D, it is not surprising that DHS never substantiated the concerns.

2. Behavioral Health Care

When an institution's behavioral health care is so poor that it exposes residents to serious risk of harm and regression, the state violates its residents' due process rights. *C.P.X. v. Garcia*, 450 F. Supp. 3d. 854, 905-06 (S.D. Iowa 2020) (noting "disjointed, wholly inadequate design of" institution's mental health programming). For the reasons set forth below, the behavioral health care at Glenwood violates residents' constitutional rights.[44]

[43] The facility Medical Director is responsible for evaluating the other PCPs. However, there is no formal process, either specific to Glenwood or applying to all of DHS, for regular evaluations of a medical director's clinical competence. As evidenced by what occurred here, a medical director with a direct caseload should be subject to some kind of ongoing clinical monitoring to assure that care is appropriate.

[44] The State is aware of and has formally acknowledged problems with behavioral health care at Glenwood, and State officials affirmed that behavioral health needs at Glenwood are not being met. While Dr. Rea was Superintendent, multiple State employees – from residential treatment workers to the Interim Superintendent and Central Office staff – raised concerns about behavioral health care, including the rate of restraints at Glenwood, to

a. Glenwood Violates the Right of Individuals To Be Free from Unnecessary Restraint

The right to be free from unreasonable bodily restraints is at "the core of the liberty protected by the Due Process Clause," *Youngberg*, 457 U.S. at 316. The State "may not restrain residents except when and to the extent professional judgment deems this necessary to assure safety." *Beaulieu*, 690 F.3d at 1032 (citing *Youngberg*, 457 U.S. at 324).

Emergency physical restraint "involves physically holding or securing a person to protect that person or others from behavior that poses imminent risk of harm."[45] Under generally accepted professional standards, more restrictive interventions like restraint should only be used when less intrusive interventions have been attempted and failed or are otherwise insufficient. Glenwood substantially deviates from this standard. As the State's Expert found, "[c]learly, Glenwood violated the right of individuals to be free from unnecessary restraint."[46] We agree.

In contrast to generally accepted practices that limit restraint usage,[47] rates of physical restraints, in which residents are held by staff, skyrocketed at Glenwood. The facility's data show that restraints increased by 301% from 2017 to 2019, going from 223 restraints facility-wide in calendar year 2017, to 895 in calendar year 2019.[48] Current and former Glenwood psychology staff reported that restraints are effectively Glenwood's go-to behavioral response, rather than an emergency or last-resort response. The increased use of restraints comes with its own set of harms, including increased risk of physical injury to residents and staff, escalation of the resident's problematic behaviors, and exposure to trauma.

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the Division Administrator and others in Central Office, and State documents reflect that Dr. Rea himself realized that Glenwood was not able to adequately serve individuals with serious behavioral health needs. However, it does not appear any serious actions were taken to improve behavioral health services during Dr. Rea's tenure.

[45] Statement on Restraint and Seclusion, Ass'n for Behav. Analysis Int'l (2010), https://www.abainternational.org/about-us/policies-and-positions/restraint-and-seclusion,-2010.aspx. Physical restraint is distinct from mechanical restraint, which is limiting movement with a device or object, and from chemical restraint, which involves using medications to restrict an individual's movement or calm an individual. Mechanical restraint is discussed below, *see infra* Section IV.B.2.a.ii, and chemical restraint is not discussed in this Notice.

[46] State's Expert Report at 14.

[47] "[A]dvances in behavior analytic assessments and interventions have made it possible to reduce many severe problem behaviors without using restraint, seclusion, or other techniques that might be considered restrictive . . . ." Ass'n of Pro. Behav. Analysts, *Position Statement on the Use of Restraint and Seclusion as Interventions for Dangerous and Destructive Behaviors: Supporting Research and Practice Guidelines* (2010), https://cdn.ymaws.com/www.apbahome.net/resource/collection/1FDDBDD2-5CAF-4B2A-AB3F-DAE5E72111BF/Support_for_APBA_Pos_Stmt_-_Restraint_&_Seclusion.pdf.

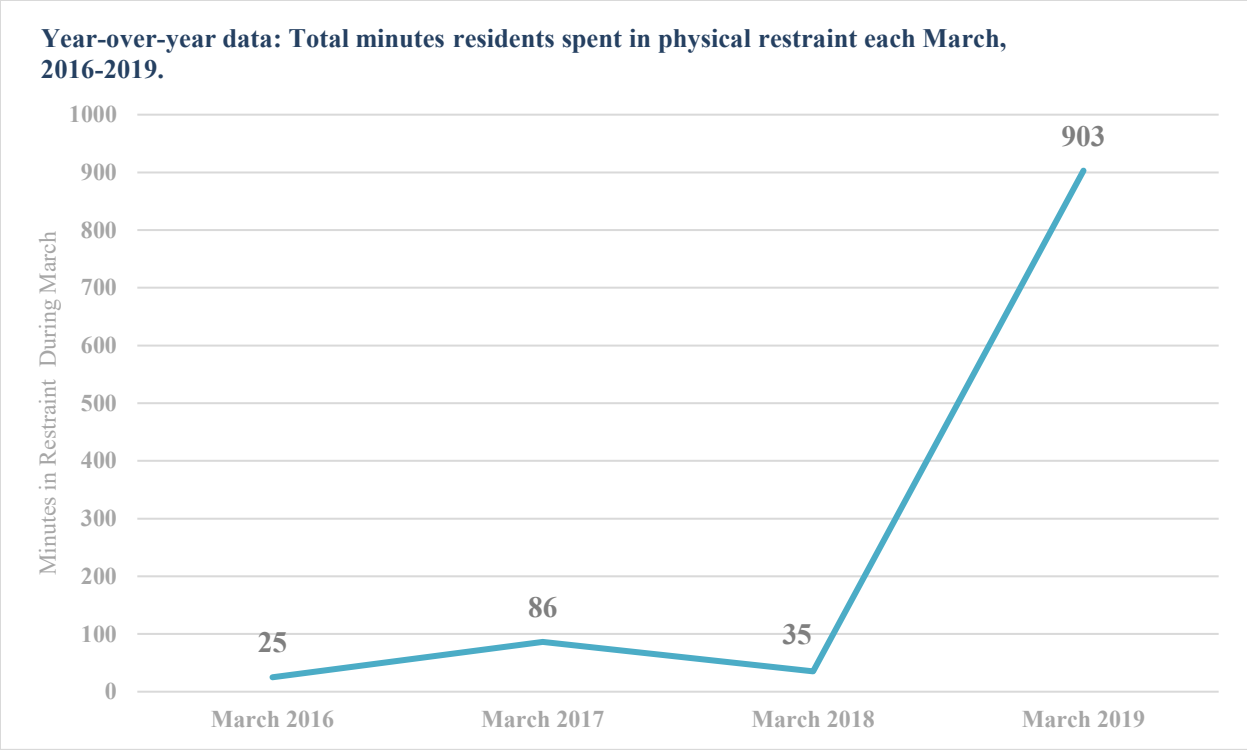
[48] DOJ received Glenwood restraint tracking logs through March 2020. Glenwood had 123 restraints in the first quarter of 2020. Limited conclusions can be drawn from only one quarter of data, but notably restraints were lower in the first quarter of 2020 than for any quarter in 2019. However, restraints for the first quarter of 2020 were more than double the quarterly average in 2017 of 56 restraints. Additionally, in those three months multiple individuals had already exceeded, or were on track to quickly exceed, restraint totals for prior years.

This spike in restraints was noticed when it began, raised by various employees, and dismissed by Glenwood's administration. For example, one Central Office official reported that, when she raised concerns with Glenwood administrators about the Center's rates of restraints, they told her that the increase was due to two recently admitted residents. In fact, other Glenwood residents were facing increases in restraints as well. This official opined that Glenwood took insufficient steps to address her concerns about restraints there and that Glenwood's current behavioral health programming cannot support restraint reduction to a feasible level.

Restraint rates exploded in 2019 for some residents. One resident, Allison Raymond, was restrained 53 times in 2017, eight times in 2018, and then 307 times in 2019. Another, Megan McDonnell, was restrained 23 times in 2017, 34 times in 2018, and 110 times in 2019. Residents newly admitted to Glenwood also faced a large number of restraints: Nathan Tarnley was restrained 73 times in less than a year; Sophie Bradley 118 times in slightly over a year; and Emily Finch 293 times in under two years.

Glenwood's restraint training manual states that, "Emergency Physical Restraints will last no longer than 10 minutes." No restraints lasted longer than 20 minutes in 2017, and only three in 2018. But in 2019, there were 97 restraints lasting longer than 20 minutes. Those restraints ranged from 21 minutes to over 100 minutes, with some residents subjected to multiple long-duration restraints in one or two-day periods. For example, three of the 17 physical restraints that resident Emma Fenton experienced in two days lasted a total of 305 minutes (5 hours, 5 minutes). Similarly, in 2019 Ms. Raymond had 24 physical restraints lasting longer than 20 minutes, including six long-duration restraints in one day that lasted for a total of 289 minutes (4 hours, 49 minutes).

Glenwood's increased reliance on restraints is also demonstrated by the total number of minutes residents spent in restraint in a particular month. In March 2016, 2017, and 2018, residents spent between 25 and 86 minutes in restraint. That number jumped to 903 minutes by March 2019.



In addition to inadequate behavioral health programming, *see infra* Section IV.B.2.b, a number of decisions regarding behavioral health and restraint policies and practices, discussed below, contributed to Glenwood's unconstitutional reliance on unnecessary and inappropriately applied restraints.

i. Glenwood's Application of Restraints Is Constitutionally Deficient and Unsafe

When restraints are applied, generally accepted professional standards govern their use and require precise, individualized criteria to determine the earliest point when it is safe to release an individual from an emergency physical restraint, careful monitoring of the use of restraints, and changes to a resident's behavior support plan to reduce the future likelihood of restraint use. Glenwood has substantially departed from these standards.

A review of Glenwood's incident reports indicates that staff lack clear criteria for the release of restraints and information about de-escalation. Further, neither the Psychology Department nor residents' interdisciplinary teams reliably monitor the use of restraints. Additionally, Glenwood does not assess staff's use of restraint as the restraint is occurring. But it is essential to have such monitoring to ensure that the crisis response procedures are being performed safely and to verify how restraints are actually implemented. Moreover, and most basically, Glenwood does not make changes to the behavior support plans of the residents it restrains to reduce the likelihood of future restraint. These deficiencies subject Glenwood residents to unsafe and needless application of restraints.

ii. A Change in Restraint Protocols Contributed to Unnecessary Restraints

One of the factors contributing to Glenwood's unconstitutional use of restraints was its change in restraint protocols. In early 2018, Glenwood implemented changes in its restraint protocols from the nationally recognized Mandt system to a new system called Crisis Interaction Training (CIT). Mandt training is well-regulated and structured, with specific criteria for becoming a Mandt trainer and conducting Mandt training. By contrast, CIT had been specifically designed for Dr. Rea's former employer, Parsons, which houses forensically involved individuals. The State's Expert has noted that "several of the [Glenwood] instructors voiced concern about CIT's lack of national recognition as a behavior management system, the lack of structure of the CIT training, and that it lacked a re-certification program."[49]

As acknowledged by the State's own review of training protocols, the Mandt system had a greater focus on de-escalation than CIT. De-escalation is an important tool in addressing behavioral disturbances to avoid or reduce the use of restraints. Inadequate de-escalation has occurred frequently at Glenwood since this change, which, among other results, led to staff resorting to restraints more quickly. Not surprisingly, the State's Expert noted that restraints increased from ten times per month to 42 times per month after the implementation of CIT, and concluded that "[i]t is clear that implementation of CIT was at least partially responsible for the increase in the use of emergency physical restraint."[50]

At the same time that Glenwood decreased training for staff on techniques to avoid restraint altogether, it also introduced more aggressive, restrictive, and dangerous forms of restraint. Before adopting CIT, Glenwood had prohibited staff from restraining residents in a supine position on the floor in almost all cases, but with the change to CIT, Glenwood permitted supine restraints, and has relied on them heavily. For example, the then-Director of Psychology described a restraint of one resident, Emily Finch, in which she was placed on her back with six people holding her down. Another resident, Sophie Bradley, has had a large number of five-person supine restraints. Other residents were subjected to three to five staff restraining them in a supine position. A staff member described what this was like in practice: one Glenwood employee would be on top of each of the resident's limbs.

When Glenwood adopted CIT, Woodward's Superintendent (later the Glenwood Interim Superintendent) told Dr. Rea and DHS officials that doing so was a step backwards. Other staff members raised similar concerns directly to the then-Director of DHS. But DHS did not address the issue, although it now agrees that CIT is ill-suited for Glenwood. After our investigation

[49] State's Expert Report at 12. Making matters worse, Glenwood's restraint training is not conducted by members of the Psychology Department but instead by individuals without any expertise in behavior analysis, crisis management, or psychology.

[50] *Id.* at 14.

commenced and the Interim Superintendent arrived at Glenwood, the Center began to discontinue use of CIT and revert to Mandt.[51]

Glenwood also changed its policy in 2019 to permit the use of mechanical restraints, which are devices that limit an individual's movement. Such restraints should only be used "to prevent otherwise uncontrollable problem behavior (e.g., self-injurious behavior) that has the potential to produce serious injury."[52] Glenwood then sought DHS approval to use mechanical restraints on Ms. Finch in response to behaviors that, even if severe in her case, did not warrant such restraints.[53] Meanwhile, Glenwood's administration actively obstructed implementation of Ms. Finch's behavior support plan. *See infra* IV.B.2.c.iii. Statements by high-level State officials and Glenwood documentation conflict as to whether DHS ever approved mechanical restraints for Ms. Finch, and we found no evidence that she was ever placed in mechanical restraints, but Glenwood had gone so far as to purchase a straightjacket, which it euphemistically referred to as a "camisole," in which to restrain her.

Glenwood's efforts to subject Ms. Finch to mechanical restraints demonstrated a willful disregard for generally accepted professional standards of care that placed its residents at needless risk of harm.

iii. The Use of Programmatic Restraints Contributed to Glenwood's Increase in Unnecessary Restraints

Another factor contributing to Glenwood's unconstitutional use of restraints was the decision to utilize programmatic restraints. In early 2019, the Department of Inspections and Appeals (DIA), the federally designated State Survey Agency responsible for inspecting and certifying Iowa's Intermediate Care Facilities, found that restraints were happening so frequently at Glenwood that they could not reasonably be classified as emergency restraints and, if restraints continued at that frequency, should be treated as programmatic and included in a behavior support plan to ensure review and approval by the interdisciplinary team. Glenwood was tasked with developing the corrective action plan in response to this finding. It could have chosen to evaluate the reason for these frequent emergency restraints, and implement changes to correct any overuse. Instead, Glenwood chose to stop limiting the use of restraints to emergencies and instead designated frequent restraints as programmatic, building them into behavior support plans. The list of residents who were subjected to programmatic restraints grew quickly, and included people who previously had not been restrained in a long time. Troublingly, these residents' interdisciplinary teams and Glenwood's Human Rights Committee

[51] As of the time of our interviews, the change back to Mandt had not yet been implemented.

[52] Ass'n for Behav. Analysis Int'l, *Statement on Restraint and Seclusion* (2010), https://www.abainternational.org/about-us/policies-and-positions/restraint-and-seclusion,-2010.aspx.

[53] An example of when mechanical restraint is appropriate is when an individual engages in head-banging behavior, which can cause serious injury, and the only way to prevent that behavior is continuous holding of the individual, such as by the use of mechanical restraint. Mechanical restraint is a restrictive intervention that carries a risk of physical harm.

acquiesced to the deployment of these restraints by approving behavior support plans that used them, despite the apparent lack of need.

Glenwood's decision to use programmatic restraints fueled the increase in restraints and appears to have reflected ideological abandonment of the belief that restraints should be limited to emergencies only. Even after a DHS official raised concerns that the number of people approved for programmatic restraints was growing, and questioned whether this was an indicator that restraints were no longer being limited to use as a last resort, programmatic restraint remained in individuals' behavior support plans (albeit fewer than before she raised these concerns). Glenwood psychologists expressed similar concerns to us, and the State's Expert reached essentially the same conclusion:

> [T]he unfortunate consequence of changing emergency restraint to programmatic restraint for a number of people may have provided staff an incentive to use physical restraint more frequently than ever before because it was now in the behavior support plans. In addition, because the behavior support plans had informed consent from the parent/guardian and review/approval by the Human Rights Committee, programmatic restraint did not have the same level of scrutiny as the use of emergency restraints.[54]

b. Glenwood Violates the Right of Individuals To Be Free from Unnecessary Seclusion

Like restraint, seclusion[55] should only be used when less restrictive interventions have failed or are otherwise inadequate. When used in an emergency, "seclusion should be implemented according to well-defined, predetermined criteria; include the use of de-escalation techniques designed to reduce the target behavior without the need for physical intervention; be applied only at the minimum level of physical restrictiveness necessary to safely contain the crisis behavior and prevent injury; and be withdrawn according to precise and mandatory release criteria."[56] In rare cases when seclusion is incorporated into a behavior support plan, the plan must "a) be derived from a behavioral assessment, b) incorporate reinforcement strategies for appropriate behavior, c) be of brief duration, d) be evaluated by objective outcome data, and e) be consistent with the scientific literature and current best practices."[57] But, though Glenwood's psychologists uniformly told us that Glenwood prohibits the use of seclusion, Glenwood has

[54] State's Expert Report at 14. While consent from parents/guardians and approval from the Human Rights Committee are critical protections, those protections were not effective here. As a DHS official noted, it was "concerning" that the interdisciplinary teams and Human Rights Committee were giving approval to implement programmatic restraints for individuals who "have not had a physical restraint in a significant amount of time."

[55] Seclusion is removal to a specific environment, isolating an individual from others to interrupt and intervene in behavior that places an individual or others at risk of harm.

[56] Ass'n for Behav. Analysis Int'l, *Statement on Restraint and Seclusion* (2010), https://www.abainternational.org/about-us/policies-and-positions/restraint-and-seclusion,-2010.aspx.

[57] *Id.*

secluded residents without those safeguards. Glenwood has assigned residents to live in isolation in homes and also placed individuals in their rooms and prevented them from leaving.

One teenage resident, Ms. Finch, who has significant behavioral issues, lived in isolation in a home for more than two years until she moved to a community placement in June 2020. She had little interaction with the outside world, and staff members informed us that they were instructed to physically block her from going outside. This resident's home was an austere environment, devoid of almost all items with which the resident could interact. Though she lived secluded in this home for more than two years, Glenwood had no real long-term plan for increasing her access to items, activities, or the outside world. By being secluded, this resident lost the opportunity to build skills, learn how to appropriately interact with others, and engage with the community. Moreover, seclusion likely worsened her existing mental health and behavioral health issues.

Glenwood has housed other residents entirely by themselves, and we found evidence that Glenwood staff placed residents in their rooms and prevented them from leaving, even though the then-Director of Psychology confirmed to us that residents are supposed to be able to leave when they want.

Because seclusion at Glenwood is used without appropriate safeguards and occurs in the absence of effective behavioral supports, it substantially departs from generally accepted standards of care.

c. Glenwood's Behavior Support Plans and Skill-Building Programs Are Deficient

Glenwood residents have a constitutional right to reasonable behavioral health care. *See Youngberg*, 457 U.S. at 319 n.1 & 323 (finding right to "reasonable training to ensure safety and freedom from undue restraint.").[58] When an institution's behavioral health care is so poor that it exposes residents to serious risk of harm and regression, the state violates its residents' due process rights. *C.P.X. v. Garcia*, 450 F. Supp. 3d. 854, 905-06 (S.D. Iowa 2020).

As explained below, behavioral health programming at Glenwood, including the development of behavior support plans, work assignments, and other skill-building programs, is constitutionally deficient and does not meet generally accepted standards of care.[59]

[58] Training, in the context of *Youngberg*, means development of needed skills. *Youngberg*, 457 U.S. at 309 n.1; *see also id.* at 318 (discussing training related to aggressive behavior in order to avoid the potential need for restraints).

[59] The State's Expert reached a similar conclusion, finding that "[m]any of the [Glenwood] behavior support programs are ineffective and substantially depart from generally accepted professional standards. In particular, they often are not based on adequate functional assessments, are poorly crafted, and are not closely monitored, evaluated, and revised as needed." State's Expert Report at 17.

i. Glenwood's Behavioral Assessments Are Inadequate

Generally accepted professional standards require that individuals with behavioral health needs have comprehensive behavioral health assessments that identify the functions of target behaviors. Functional assessments are the basis for the individual's behavioral programming and must be based on current data. Glenwood substantially departs from these standards. Indeed, the State's Expert concluded that Glenwood's functional assessments have "significant shortcomings,"[60] and the Interim Superintendent of Glenwood admitted she is concerned that assessments are not sound. Glenwood's behavioral health assessments are deficient for a number of reasons.

First, Glenwood relies on inadequately trained psychology assistants, rather than psychologists, to conduct key elements of the assessment. Second, the data that Glenwood gathers for behavioral assessments do not allow it to identify the temporal relationship between antecedents, behaviors, and consequences or include context sufficient to understand the behavior. Without such data, Glenwood's functional behavioral assessments do not provide treatment teams with useable information to develop an accurate understanding of the behavior, and behavioral interventions flowing from these assessments are, at most, best guesses. As a result, Glenwood's assessments are often inconclusive, and they frequently either do not identify the function of particular behaviors or cluster multiple behaviors, functions, and interventions together.[61] Third, new data is not reliably incorporated into assessments, and assessments do not inform appropriate changes to behavioral interventions when residents' behavior is worsening. The State's Expert noted that annual updates "may not be sufficient given possible changes in function of behaviors over time."[62]

For these reasons, Glenwood's behavioral assessments cannot be relied on in developing, assessing, or revising behavior support plans, which means that Glenwood cannot reliably deploy correct behavioral interventions.

ii. Glenwood's Behavior Support Plans Are Inadequate

Under generally accepted professional standards in behavioral health care, a behavior support plan is a document that guides an individual's treatment and identifies target behaviors and the function, or purpose, of each challenging behavior. Behavior support plans should be based on adequate assessments, s*ee supra* Section IV.B.2.c.i, and current data, and they should be updated as warranted based on timely analysis of that data. They should provide

[60] *Id.* at 18.

[61] The then-Director of Psychology suggested that data collection and analysis were unnecessary because most residents had lived at Glenwood for many years, despite the fact that residents' behaviors are generally not well managed. *See infra* Section IV.B.2.c.v. Residents' worsening conditions indicates that those behaviors, and their antecedents, are actually not correctly understood. However, he justified Glenwood's inadequate data collection and analysis by saying that, even if Glenwood learned additional information about the behavioral needs of the resident, it would not be able to implement a more finely tuned behavior support program.

[62] State's Expert Report at 17.

comprehensive instruction to the staff who interact with the individual regarding how and when the challenging behaviors arise and interventions to minimize the behavior. For each target behavior in a behavior support plan, the treatment team should identify a replacement behavior that serves the same function as the target behavior but is not harmful. Behavior support plans should also instruct staff how to reinforce positive behaviors. They should promote the least restrictive interventions to the extent possible. As described below, Glenwood's behavior support plans substantially depart from generally accepted professional standards.

Glenwood's behavior support plans do not identify and provide adequate interventions for all problematic behaviors targeted for improvement (target behaviors), do not fully operationalize or describe interventions to ensure consistent implementation across all staff, do not identify replacement behaviors, do not utilize reinforcers properly, are overly restrictive, and are not calibrated to respond to emerging behaviors. The State's Expert agrees, concluding that behavior support plans substantially depart from professional standards because they "are poorly crafted, and are not closely monitored, evaluated, and revised as needed."[63]

For at least some residents, Glenwood's behavior support plans do not address residents' highly disruptive behaviors. Glenwood's behavior support plans frequently fail to both identify the oncoming signs, or precursors, of target behaviors and concrete steps that staff should take to intervene or de-escalate the situation before those behaviors commence. When plans do identify precursors, they often do not provide useful guidance on how to intervene.[64] Similarly, our investigation revealed that, even if a person is experiencing multiple problematic behaviors, Glenwood's behavior support plans provide only one replacement behavior, due to insufficient resources and staff skill levels, and that replacement behavior is not necessarily commensurate with the resident's skills.

Similarly, the State's Expert noted concerns with psychologists' ability to adequately identify appropriate replacement behaviors and concluded that "the identified replacement behaviors were often too broadly stated to be useful. For instance, the behavior support plan for one individual indicated that the identified replacement behavior for . . . engaging in 'socially inappropriate behavior,' was to engage in 'appropriate social behavior.'"[65] For a behavior support plan, this language is meaningless. Glenwood's failure to identify functionally equivalent replacement behaviors and teach those behaviors to its residents serves to maintain residents' problematic behaviors.

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[63] *Id*.

[64] For example, one plan had the exact same protocol for responding to incidents of self-harm, leaving assigned area, property destruction, aggression, and social disturbance. More particularly, the plan's response was the same for self-harm caused by skin picking, which is typically understood to be an involuntary habit, as for other types of self-harm, even though the standard treatment for each of these is quite different.

[65] State's Expert Report at 18.

In addition to depending on limited replacement behaviors, Glenwood utilizes a limited set of reinforcers.[66] Staff told us that, when Glenwood previously had access to a budget for reinforcers, staff were able to provide items to residents that they viewed as meaningful, like a special outing to get a preferred meal, when the residents earned them through positive behavior. Currently, the reinforcers available to residents primarily consist of spending time with preferred staff.

The lack of reinforcers diminishes residents' incentive to participate in skill acquisition and other programming. Further, Glenwood undercuts the strength of these reinforcers by delaying providing them. For example, some behavior support plans require a person not to engage in a behavior for a week or more before earning a reinforcement. This requirement is problematic for people with IDD, who may not be able to sustain appropriate behaviors for that long without more frequent rewards, especially when the appropriate behavior is first being learned.

In addition, Glenwood's behavior support plans do not focus on building adaptive skills, and instead emphasize restrictive measures, such as one-to-one level of supervision, which can be harmful if used unnecessarily because they decrease individuals' ability to develop independence and social skills beyond engaging with the staff member who is assigned to supervise them closely. The then-Director of Psychology confirmed that Glenwood residents have been placed and maintained on increased level of supervision in unnecessary and even counter-productive ways. Another staff member described an individual who was on one-to-one supervision for self-harming behavior without a plan to reduce the supervision, even though the resident does not have frequent or serious self-harm. A Glenwood official separately shared with us examples of four Glenwood residents who could have had their one-to-one supervision reduced, but did not.

Behavior support plans are not calibrated to respond to emerging behaviors, or declines in behavior. For one individual, Sophie Bradley, her records contained little behavioral data, and despite at least a twenty percent increase in problematic behaviors over the course of three months, there were no apparent substantive changes to her behavior support plan. Furthermore, her restraint logs indicate that the procedures staff are directed to take when her behavior is escalating make the behavior worse and lead to her being restrained.

iii. Glenwood's Behavioral Interventions Are Inadequately Implemented and Monitored

Generally accepted professional standards require behavior support plans to be implemented as written. Staff who are responsible for implementing behavior support plans also need to receive adequate training on the specific plan to ensure that the plans are implemented correctly. Training should be conducted by staff who are demonstrably competent to do so and

[66] Reinforcers are "[e]vents that increase the likelihood of a behavior occurring in the future." Compar. Cognition Lab'y, Dep't of Psych. and Brain Scis., Univ. of Iowa, *Reinforcement*, https://psychology.uiowa.edu/comparative-cognition-laboratory/glossary/reinforcement (last visited Aug. 27, 2020). They are used to promote positive behaviors.

require staff to successfully replicate the procedure in training before they do so with residents. Further, staff implementation of behavior support plans must be monitored sufficiently to ensure plans are implemented correctly, with staff receiving correction or retraining as warranted.

Glenwood's implementation of behavioral interventions substantially departs from generally accepted standards. The assessment of the State's Expert confirms this finding: "[Glenwood] does not have an acceptable system to assess effective implementation of behavior support plans, staff's knowledge of the plan, and correct documentation to assess progress. Without the necessary teaching, monitoring and evaluation, individuals are in danger of being subjected to inadequate and unnecessarily restrictive treatments."[67]

Glenwood's leadership interfered with behavioral interventions for individual residents, which led to Glenwood's behavior support plans being inadequately implemented. Psychologists told us that administrators—in particular Dr. Rea—disregarded the behavior support plans of multiple residents with serious behavioral health needs.[68] For example, administration officials, including Dr. Rea, would reportedly offer resident Emily Finch anything she wanted, including food in excess of her dietary plan, which led to her weight increasing.[69] The then-Director of Psychology told us that he was "clearly convinced" that Glenwood created most of Ms. Finch's problems, partially due to the disregard of her behavior support plan. Administrators continued to undercut residents' behavior support plans even after staff reported their actions to the Department of Inspections and Appeals and the facility was cited for them.

In doing so, Glenwood's administrators also completely bypassed the interdisciplinary teams responsible for approving and implementing plans. These high-level administrators' actions fostered a counter-therapeutic environment, with ever-increasing behavioral problems, and inhibited residents' opportunity for future community integration. Interference with and lack of implementation of residents' behavior support plans also contributed to an increased rate of restraint at Glenwood.

Behavior support plans are also not implemented adequately because staff responsible for their implementation lack sufficient training. Glenwood sharply reduced general training for residential treatment workers on overarching behavioral issues and restraint use,[70] and residential

[67] State's Expert Report at 21.

[68] Such willful disregard of plans is unusual from experienced administrators and is damaging to both residents and staff members.

[69] These were not the only times that Glenwood's administration circumvented residents' plans. While Dr. Rea was Superintendent, Glenwood created the "Wildly Independent Goals" (WIG) process, which was a separate interdisciplinary process to focus on specific individuals. One of the goals of the WIG process was to ensure Glenwood programming was more person-centered, which is laudable. However, the WIG process often did not include individuals' interdisciplinary team members and removed clinicians from critical service planning decisions. The State's Expert noted his "impression that the WIG workgroups took on a life of their own and unfortunately replaced the interdisciplinary team process in addressing individual needs and supports." State's Expert Report at 6.

[70] A former psychologist told us that the training requirements from the DOJ consent decree in 2003 had been torn apart. The changes to training were initiated by Dr. Rea and pursued over the concerns of staff.

treatment workers are also receiving insufficient training on individual residents' specific behavior support plans. Further, the training of "pulled staff"—staff who are working in a home different than the one they are typically assigned to—consists of a brief overview of the behavior support plan for each resident in the home, given within a couple hours of starting work in the home. This amount of training for complex plans is insufficient. Staff told us that pulled staff sometimes work with individuals for whom they have received no training.

Inadequate staff training has adverse consequences for residents. Staff reported that residential treatment workers, psychology assistants, and treatment program managers are unprepared to work with particular individuals who have high behavioral health needs. We interviewed a direct care worker who was clearly unaware of significant behavioral issues experienced by the residents she serves. And staff told us that inadequate training has led to residents being restrained unnecessarily.

Additionally, Glenwood lacks reliable mechanisms to ensure that behavior support plans are implemented correctly, as acknowledged by Glenwood's Interim Superintendent and then-Director of Psychology. The State's Expert has also expressed concern about the State's ability to monitor implementation of behavior support plans. Staff, too, reported that behavior support plans are monitored infrequently and using an inadequate methodology, at least for some residents. As a result of these failings, Glenwood is unable to determine whether staff actually know how to implement the behavior support plans.

iv. Glenwood Inadequately Engages Its Residents

Another essential component of behavioral health services for individuals with IDD is that residents should have access to activities during the day that they experience as productive and meaningful, like the opportunity to work. When people with IDD are not engaged in activities that they experience as meaningful, they are more likely to engage in maladaptive behaviors and cause harm to themselves or others. Engaging people with IDD in meaningful activities is also the basis for skill building and development of autonomy and independence. As the State's Expert noted, "[g]enerally accepted professional standards recognize that everyone deserves a meaningful life filled with opportunities for fun, personal growth and individual satisfaction."[71] As described below, Glenwood has substantially departed from these standards.

Our investigation revealed that individuals at Glenwood spend extensive periods of the day unengaged, without activities or any structured programming occurring. According to the State's Expert, Glenwood staff have expressed frustration that they are unable to provide residents with meaningful things to do, including work, because of staff shortages and vacancies. The Interim Superintendent acknowledged this lack of day activities, noting that the essentials of active treatment at Glenwood have been forgotten.

The State reported that, though there are 79 Glenwood residents who have jobs at the facility, many are scheduled to work less than two hours on the days they are scheduled to work.

[71] State's Expert Report at 27.

Some residents are scheduled for only one hour of work per week. Residents' jobs are often not meaningful to them. A Central Office official expressed concerns to us that residents' jobs are not based on their preferences or interests and are not teaching them skills. The State's Expert noted that, while for some individuals the work opportunities are meaningful, the options are limited for other individuals "due to staff resources and lack of jobs that individuals find interesting."[72] Additionally, some staff told us that Glenwood decides that some individuals will "retire," or stop working, if they are insufficiently productive, regardless of their work preferences.

Nor are other meaningful activities, such as proactive programming or recreation, available for residents throughout campus. Especially for houses where many individuals are in wheelchairs, residents do not get enough access to campus activities and often do the same thing every day, e.g., playing Uno. Going off campus for activities was even more rare—the State's Expert noted that most individuals only leave campus for community outings once or twice per month, and some staff stated that residents with whom they worked could not leave campus at all due to vacant staffing positions. Despite having an awareness of these issues, the Central Office has not taken steps to ensure that individuals are engaged in activities.

Glenwood also fails to ensure that residents receive opportunities to learn new skills. The then-Director of Psychology noted that Glenwood's skill-acquisition programs were not run at set schedules, but instead were left for when staff had an opportunity to implement them during the day. The State's Expert found significant shortfalls in the development and implementation of skill-acquisition planning:

> Skill-acquisition programs in behavior support plans are severely lacking. . . . It appears that direct support staff are left to create their own teaching strategies, with poor success. The only written guidance to staff found in BSPs are vague statements about encouragement. The behavior plans say nothing about which teaching strategies to use or avoid with the individuals based upon assessment of their skills.[73]

This haphazard provision of skills training is a substantial departure from generally accepted standards for people with IDD. Glenwood is obligated to provide them an "aggressive, consistent implementation of a program of specialized and generic training," 42 C.F.R. § 483.440(a)(1), but is clearly not doing so.

v. Glenwood Residents Are Harmed by Glenwood's Inadequate Behavioral Health Care

As a result of the aforementioned deficiencies in Glenwood's behavioral health care, residents suffer harms such as restrictive interventions and regressions to their behavioral health. In a behavioral health program that meets constitutional standards, one would expect to see

[72] *Id*.

[73] *Id.* at 26.

decreases in target behaviors, but these behaviors significantly increased at Glenwood. Furthermore, residents' opportunities to live successfully with greater autonomy have been sabotaged by a dysfunctional system. Indeed, the State's Expert noted that the number of problematic behaviors is evidence that the behavioral programming is deficient: "Although some persons newly admitted to a facility might arrive with serious maladaptive behaviors, the fact that a significant number of the [Glenwood] population engages in serious maladaptive behaviors demonstrates that the facility's behavioral supports and services suffer from major deficiencies."[74]

As discussed above, *see supra* Sections IV.B.2.a and IV.B.2.b, Emily Finch is a teenage former resident of Glenwood[75] who was restrained 293 times between January 2018 and November 2019, and was secluded in a house by herself for more than two years. While at Glenwood, she continued to have many significant behavioral incidents. The then-Director of Psychology acknowledged that Glenwood "created a lot of problems" for this resident and made her situation worse. She was not served in the most integrated environment appropriate to her, and she has lost the opportunity to build social and other skills and engage with peers and the community.

Similarly, Sophie Bradley's harmful behaviors became so severe that staff warned Glenwood's management she might harm her housemates, whose fear of her triggered their own behavioral outbursts. But Glenwood's management did not act until staff complained to the Department of Inspections of Appeals, and that action was limited to moving Ms. Bradley to a new house. Her new house staff members lack experience serving people with complex behavioral health needs and do not appropriately intervene or deescalate when problem behaviors start. But without such intervention, her self-injurious behavior intensifies, resulting in staff physically restraining her at high rates and subjecting her to other restrictive interventions. These include an increased level of supervision, which has placed particular staff members in close physical proximity to her throughout each day, monitoring all of her movements and behaviors.

Other residents' behavioral health problems have also increased, leading to a declining quality of life for residents throughout campus. We learned that one resident, Ruby Crenshaw, had been subjected to a restrictive one-to-one level of supervision and was limited to particular areas of her house. Staff reported that Ms. Crenshaw and all of the other residents in that "high chaos" home had experienced regressions in behavior, and some of them were increasingly restrained and undergoing other restrictive interventions. Staff working in another house told us that an individual, Stanley Jackson, had recently had serious behavioral episodes that affected others in his house, was not getting the support he needs, and had experienced increased restraints. Among the consequences of these residents' unmet behavioral needs is triggering

[74] *Id.* at 17.

[75] Ms. Finch moved into a community placement in June 2020.

other residents to engage in "copycat" behaviors and diminishing residents' ability to act with independence.

d. Glenwood's Behavioral Health Department Is Structurally Deficient and Fails To Consider Data, Professional Opinion, and Potential Consequences in Making Decisions

In addition to the substantive deficiencies identified above, the Psychology Department at Glenwood has structural and staffing issues that contribute to its inability to adequately serve individuals with behavioral health needs.[76] Glenwood's overall failure to consider data, professionals' opinions, and potential consequences in making decisions also has serious deleterious effects on behavioral health services.

Staffing deficiencies in the Psychology Department inhibit Glenwood's ability to care for residents with behavioral health needs.[77] The lack of psychologists credentialed in behavioral analysis at Glenwood is particularly problematic.[78] There is also an admitted inability to provide counseling, group therapy, and sex and relationship education for its residents. And the State's Expert expressed concerns about Glenwood's treatment of individuals who had a history of trauma: "[Glenwood] does not have a current system of trauma-informed care, but must develop a comprehensive approach to trauma-informed care at both the clinical and organizational levels to be successful."[79] Overall staffing shortages mean, as Glenwood's then-Director of Psychology admitted, that even if the behavior support plans were improved, the facility lacks staff to implement better tailored programs. Until the staffing situation is under control Glenwood will continue to struggle with residents who have complex behavioral health needs. Collectively, these staffing issues significantly diminish Glenwood's ability to provide effective behavioral supports to people who need them, increasing residents' risks of harm.

Structural issues in the Psychology Department and in Glenwood as a whole undercut communication on matters vital to resident care. As noted below, Glenwood's psychologists have little control over much of the facility's behavioral programming, because they do not oversee the psychology assistants, who are under-trained for the task. *See infra* Section IV.C.1.

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[76] At Glenwood, residential treatment workers, psychology assistants, and treatment program managers are not required to have any specialized education, licensure, or certification related to psychology or behavioral health. Individuals with the title of "psychologist" at Glenwood may qualify with a master's degree in psychology, behavior analysis, or counseling and two years of clinical work, or with a doctoral degree in psychology, behavior analysis, or counseling.

[77] As of the drafting of this Notice, Glenwood was facing additional staffing deficiencies: the then-Director of Psychology and three psychologists all had left GRC or planned to by fall 2020, leaving only three psychologists on staff. The departing psychologists were assigned to the majority of residents with the highest behavioral needs, and their departures will lead to disruptions in care. None of the remaining psychologists has a certification in behavioral analysis.

[78] Two psychologists had education and training in mental health. These skills could have been useful with many individuals at Glenwood, but our review indicated that these skills were not properly utilized.

[79] State's Expert Report at 19.

A psychologist told us that one of the challenges of working at Glenwood was the lack of communication in decision-making, both regarding broader policies, and changes for particular residents. For example, changes to medications that affect resident behavior are not appropriately shared with staff. *See supra* Section IV.B.1.c.

Psychologists also told us that their concerns were not valued or responded to by leadership. For example, although some Glenwood residents engage in suicidal threats, multiple members of the facility's behavioral staff report that they are untrained and unprepared to perform an adequate suicide assessment. Yet, Glenwood's suicide policy makes them responsible for performing these assessments, even though that task is beyond their scope of practice. They stated that they had repeatedly raised these concerns to Glenwood's leadership, to no avail.

Another reason for the inadequate behavioral health care at Glenwood is that decisions and policies affecting residents' behavioral health care are made with a stunning lack of deference to professional input, reliable data, or potential consequences. Over the past few years at Glenwood, behavioral health policies, as well as more general policies affecting residents' behavioral health—some of which were put in place due to DOJ's first involvement with Glenwood—were dismantled at the direction of administration.[80] Glenwood's administration changed behavioral health policies quickly, in a blanket and non-individualized manner, and without communication with behavioral health staff or consideration of objective indicators or potential consequences. Some of these changes mandated that residents' behavior support plans change abruptly, with no individualized consideration of the impact of those changes on residents.

For example, psychologists, residential treatment workers, and treatment program managers reported to us that Glenwood's administration made the "rash" decision to move a group of women, who were housed together and had significant behavioral health needs, from the area of Glenwood that focuses primarily on behavioral health conditions to the area that focuses on medical conditions. This decision caused numerous disruptions in residents' lives because they lost supports, including familiar and knowledgeable staff. Staff members told us that as a result of this change, these women experienced regressions in behavior, lost opportunities to engage in independent activities, were restrained at increased rates, and were living in a house in chaos.

[80] These policies were removed due to Dr. Rea's expressed aversion to policies. A non-behavioral health supervisor informed us that the management at Glenwood was the worst management that person had ever experienced, partially due to a lack of appropriate policies.

C. Inadequate Staffing and Quality Management Subject Residents to Serious Risk of Harm

To function properly and provide constitutionally adequate care, an institution like Glenwood must have adequate and adequately trained staff. Further, the actions and activities of those staff members must then be subject to monitoring and oversight by a quality management system operating consistent with generally accepted professional standards. Such a system collects and analyzes reliable data to measure the institution's performance, takes preventative, corrective, and improvement steps when needed, and monitors the efficacy of those steps. As described below, Glenwood fails in both regards. These failures contributed to all of the violations described in this Notice.[81]

1. Glenwood Lacks Staff in Sufficient Numbers and Quality To Serve Its Residents

Glenwood has insufficient and underqualified staff to meet the needs of Glenwood's residents. Using industry standards to estimate needed staff, the State's Expert calculated a shortage of more than 100 funded direct-care staff positions, assuming all existing funded positions were filled – which they are not. In addition, staff working with residents often are not sufficiently trained to do so, because they are temporarily reassigned, or "pulled" from another living unit at Glenwood, which the Interim Superintendent described as a "training and implementation nightmare." The staffing shortages unsurprisingly lead to staff burnout and high turnover, which in turn means, as the State's Expert concluded, that Glenwood "cannot adequately identify risks and ensure residents' safety."[82] Buttressing that assessment is that, as the rate of professional staff departures has escalated in recent years, *see infra* Section IV.C.2, medical, behavioral, and other care for Glenwood residents has declined.

Further, Glenwood's lack of effective staff oversight worsens this problem and fosters unaccountability in several critical ways. For instance, psychology assistants are responsible for a large portion of residents' behavioral health programming, but they do not report to anyone in the Psychology Department, and psychologists do not have oversight over the psychology-related tasks they perform. Similarly, certified medical assistants (CMAs) administer medications under delegated nursing licenses, but the CMAs do not report to and are not accountable to the nursing department.

2. Glenwood Abandoned Quality Assurance and Ignored Multiple Warnings of Harm

The State does not dispute that quality assurance does not occur at Glenwood, and that Glenwood's quality management department does not have the necessary skills or time to do so.

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[81] Typically, in the realm of IDD services, the single biggest cause of bad outcomes is not the actions of individual staff but the system in which they work. *See, e.g.*, Steven D. Staugaitis, *Risk Management System Design in Developmental Disabilities* 3 (2015).

[82] State's Expert Report at 23.

Glenwood's director of quality management, who was promoted into the position without warning or training, told us that the bulk of the quality management department's work is conducting abuse investigations. She said that she had no training or experience in quality management and that she was given no guidance in operating the department.

Further, as noted above, beginning in 2018 Glenwood systematically eliminated many of its policies and procedures, including those that promoted health and safety. Staff told us and DHS that Dr. Rea frequently stated that this action was intended, at least in part, to limit Glenwood's exposure to DIA citations for policy noncompliance. Although Glenwood had developed an extensive list of measures for resident outcomes, called "quality indicators,"[83] it had stopped collecting data on some of them. And, while we saw some evidence of Glenwood staff making use of certain quality indicators in an effort to identify trends, such as falls or restraints, as a whole Glenwood does not integrate and analyze useful data to identify and remediate trends. To the contrary, from at least 2017 onward, the Quality Council (consisting of Glenwood leadership) received monthly reports containing data indicating grave harms to Glenwood residents without ensuring corrective actions were taken.

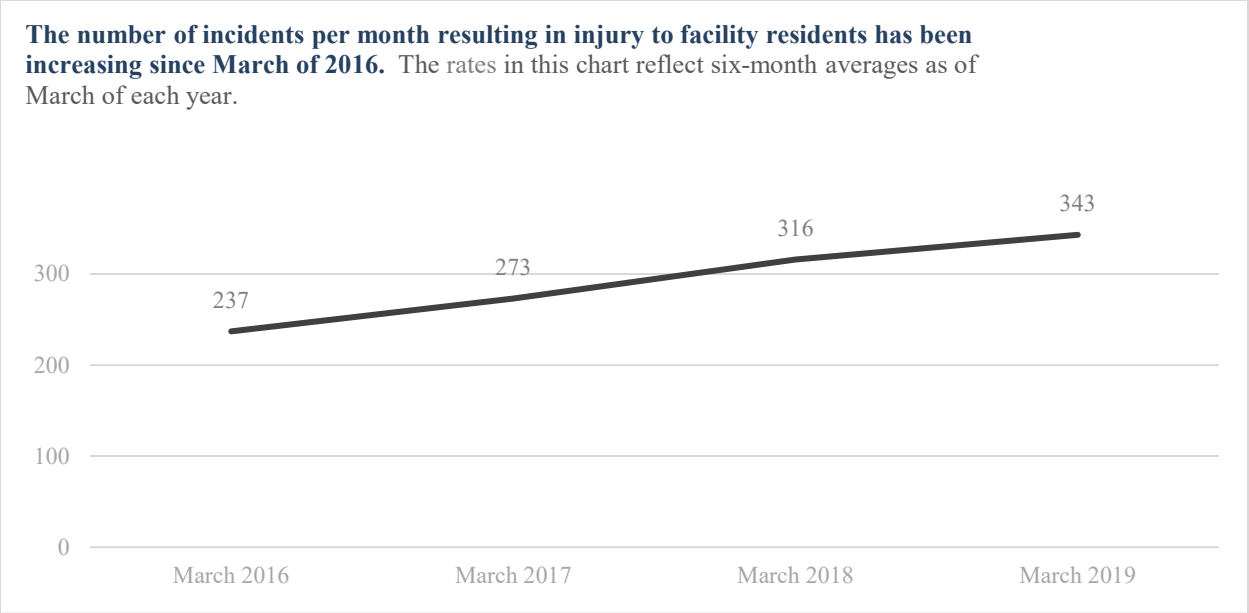
Most notably, Glenwood's data indicate that the resident death rate nearly doubled each year between April 2015 and March 2019. *See supra* Section IV.B.1.a. This trend should have prompted intensive inquiry and response, but Glenwood ignored it, and the State dismissed its significance in response to legislative inquiries. Other data should have prompted interventions but did not. For example, incidents per month resulting in injury to Glenwood residents have been climbing steadily from March 2016 through March 2019, according to Glenwood's data.[84]

[83] This work was done as part of Glenwood's successful effort to meet the requirements of a consent decree with DOJ regarding conditions in the facility. That decree was terminated in 2010, after DOJ determined that Glenwood and WRC had complied with its terms.

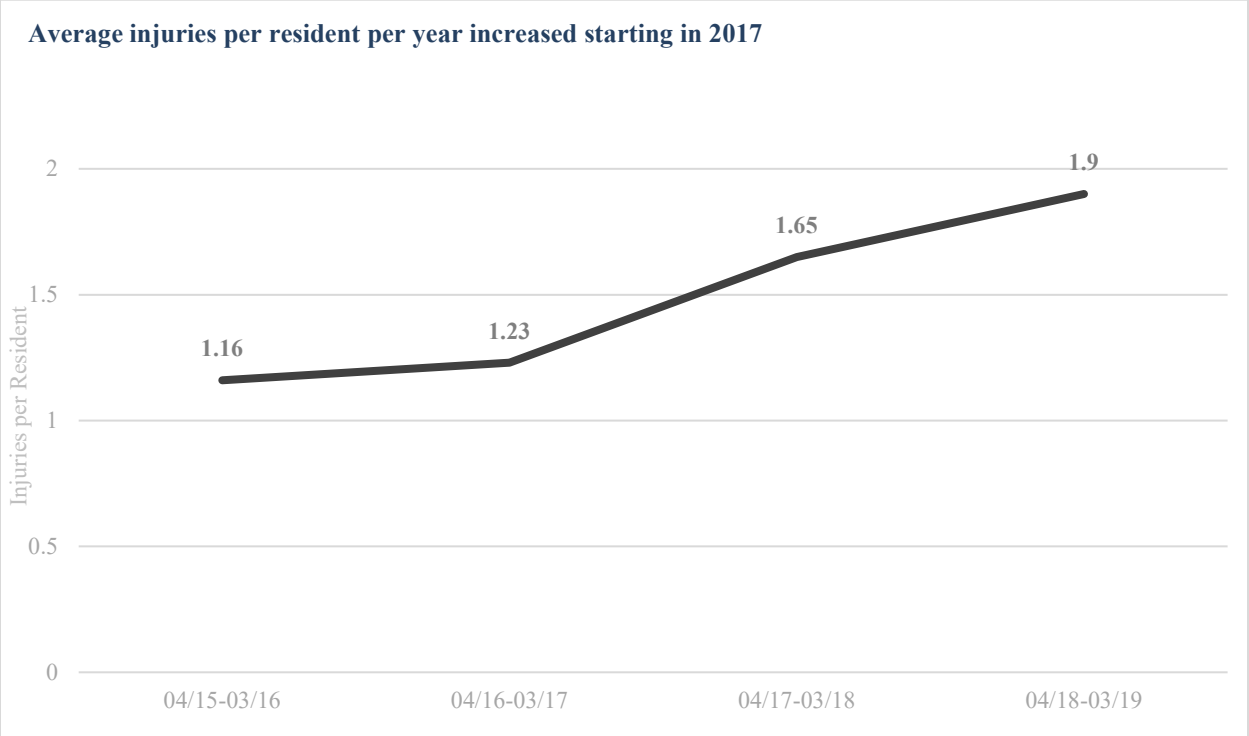
[84] Glenwood tracks the cause of staff injuries but not resident injuries. As the State's Independent Expert noted:

> In 2019, the number of staff injuries associated with the use of physical restraint increased by 466% from the previous year. In addition, 65% (33/51) of those injuries occurred when supine physical restraint was used.
>
> . . . .
>
> It was expected that residents' injuries related to use of physical restraint would show a similar pattern of injuries as noted for staff injuries. GRC does document resident injuries and the use of restraint but they are not in a database that allows for detailed review and critical analysis of their relationship. . . . It is unusual that a facility would track such a relationship for staff, but not for residents.

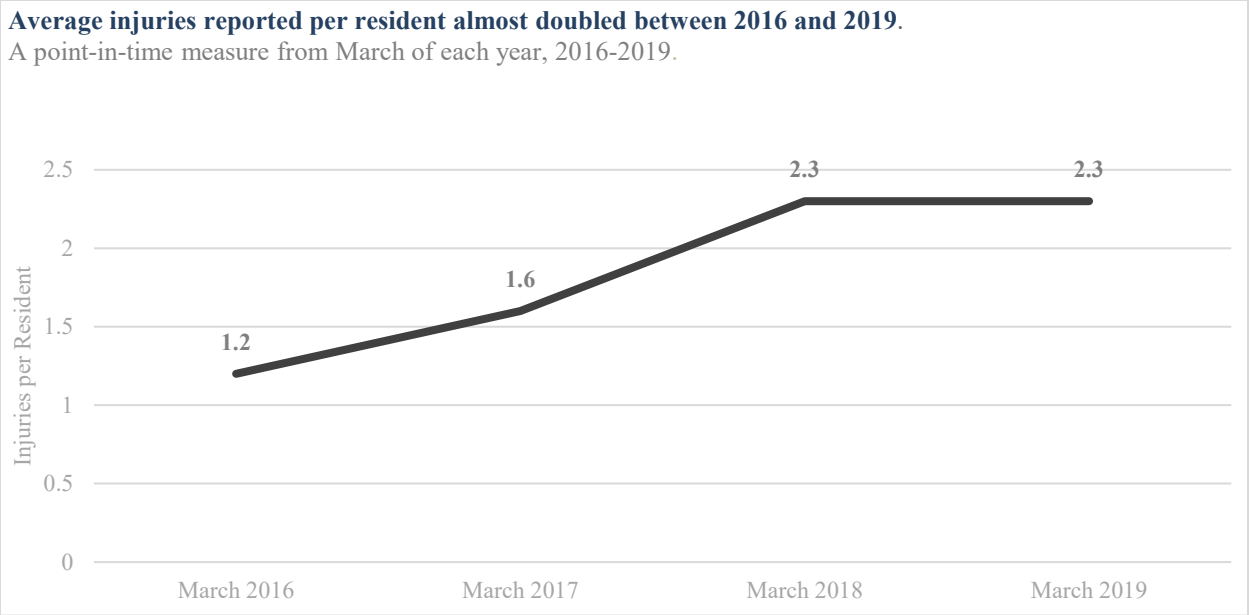
State's Expert Report at 15.



Further, Glenwood's Office of Quality Management "Outcome and Analyses" Reports ("Quality Reports") show that average injuries per resident per year sharply increased in 2017 and have continued to climb.



Finally, point-in-time measures in Glenwood's Quality Reports show that average injuries per resident have almost doubled since 2015, and rose steeply beginning in 2017.



Meanwhile, staff injuries have also been increasing dramatically for years.[85] Most notably, staff injuries from physical restraint rose 466% from 2018 to 2019.[86] These trends in injuries to residents and staff are remarkable, and should have provoked inquiry into their cause and aggressive steps to address them.

Moreover, when data is presented to the Quality Council that is facially unreliable, that, too, is unaddressed. For instance, Glenwood's March 2019 Quality Report stated that 89 unique individuals, or approximately 40% of Glenwood's population, had experienced a pressure sore in the preceding twelve months.[87] That staggering statistic should have prompted an urgent inquiry to determine if it were accurate (and what changes were needed to physical health care), or inaccurate (and what changes were necessary to ensure accurate data collection and reporting). But, according to the minutes of the Quality Management meeting, this statistic prompted no discussion. In fact, Glenwood's collection and analysis of data is so admittedly unreliable that the Quality Management Director confirmed that Glenwood would be unable to know if there was a spike in aspiration pneumonia.

The absence of reliable mechanisms to address harm to Glenwood residents led several staff to take the extraordinary step of filing complaints, styled as "grievances," on behalf of

[85] According to the *Des Moines Register*, staff injuries have been rising steadily for some time, with 69 in 2016, 82 in 2017, and 89 in 2018. Tony Leys, *State's Glenwood institution faces $60,000 fine after disabled patients injure workers*, DES MOINES REG. (May 24, 2019, 10:20 PM), https://www.desmoinesregister.com/story/news/health/2019/05/24/iowa-glenwood-resource-center-fined-worker-safety-flaws-osha-afscme-patient-deaths/1219980001/.

[86] State's Expert Report at 15.

[87] However, data collected by Glenwood as part of our investigation showed 22 pressure ulcers affecting 14 individuals.

residents[88] to bring attention to concerns about deficient care. For example, a group of staff filed an HRC Complaint asserting that one resident did not receive appropriate medical care before he died in September 2018, noting that "maybe if [he] was treated sooner or taken more seriously there would have been a different outcome." Separately, as noted above, *see supra* Section IV.B.1.a, direct support staff were so disturbed that Glenwood waited two days to assess and detect Isaac Percy's broken femur that they filed an HRC Complaint on his behalf.[89] These examples make clear that Glenwood staff have no confidence in the facility's own quality assurance processes to address deficiencies.

These examples also make clear that the HRC complaint process was not effective in addressing concerns about poor medical care.[90] Although groups of staff banding together to file such complaints is unusual, the complaints did not prompt any special attention or inquiry. The HRC complaint process did not appropriately address concerns about improper medical care because the process lacked access to doctors who could provide independent validation or critique of the care that Glenwood's PCPs had actually provided. The result was a series of complaints deemed "resolved" by the Committee or other Glenwood leadership after the PCP provided an unchallenged justification of their actions and often after Glenwood leadership told staff to defer to the judgment of the PCPs.

The State does not dispute that DHS staff did not appropriately respond to these complaints, in part because DHS leadership was reflexively dismissive of questions or information that could reflect poorly on DHS. The fact that so many employee concerns were raised directly with Director Foxhoven, but not meaningfully acted upon, shows there were breakdowns in the reporting structure that employees should have been able to use to raise issues with confidence.

The Glenwood staff who did submit HRC Complaints, or who made complaints to Glenwood and/or DHS leadership, were a small minority of staff. Many more Glenwood staff were intimidated out of even raising their concerns, out of a pervasive fear of retaliation at all staffing levels in Glenwood. One staff likened it to having a "bullseye on your back," calling

[88] Grievance is a term used in at least two contexts at Glenwood: employment disputes between employees and Glenwood, and complaints made by or on behalf of Glenwood residents to Glenwood's Human Rights Committee. For clarity, we refer to the latter as "HRC Complaints."

[89] In response, Dr. Rea reprimanded these staff for challenging decisions made by Glenwood's medical providers, asserting that staff should not raise such concerns because doing so was "disrupting staff," according to a memorandum to file describing the incident.

[90] A protocol put into place at Glenwood in 2017 was intended to ensure that staff concerns about medical care were raised and addressed. At the time DOJ began its investigation, the protocol had not worked to ensure that all staff concerns about inappropriate medical care were promptly raised within the chain of command. A new policy on IDT Conflict Resolution was added in early 2020. However, the policy is insufficient to ensure that staff concerns about clinical care are appropriately addressed and resolved. The Superintendent or Director of Quality Management is the final arbiter of disputes, which is inadequate when the disagreement relates to a clinical decision which should be resolved by a subject matter expert. Indeed, a recommendation from one of the external mortality reviews noted that, with respect to end of life care, consultation with a subject matter expert can be "particularly helpful when there are questions and/or disagreements about switching the goals of care."

Glenwood "a scary place." Multiple staff recounted repeated threats to fire professional staff who disagreed with Glenwood leadership and to have their professional licenses terminated. And many experienced administrative and professional staff resigned or were fired during Dr. Rea's tenure, including two of Glenwood's three doctors, the Administrator of Nursing, the Pharmacy Director, the Quality Assurance Director, the Assistant Superintendent, and both Treatment Program Administrators. In interviews with DOJ throughout 2020, staff described ongoing fear that raising concerns about resident well-being could cost them their jobs. Referring to interactions with Glenwood's administration, one residential treatment worker told us that staff often do not know whether to "watch [their] back or watch [their] clients." This is a choice that puts Glenwood residents at unacceptable risk of harm.

a. Glenwood's Mortality Review Process Is Inadequate

Glenwood not only lacks an effective mortality review system, it affirmatively ignored and suppressed legitimate clinical concerns regarding health care. When a Glenwood resident dies, a number of reports and reviews are generated. The Quality Management Department conducts what it calls a "Type 1" investigation – the same kind of investigation it undertakes when looking into allegations of abuse or neglect. The Glenwood investigator completing this investigation does not have access to a medical provider, other than the individual's PCP, to ask for guidance about the appropriateness or quality of physical health care provided. None of the Type I investigations for 28 deaths occurring between 2017 and 2019 identified even one concern or question regarding medical care.

In addition, the PCP conducts a review of the medical care s/he provided, and a nursing supervisor conducts a review of the nursing care provided. For any "unexpected" death, a second PCP does a so-called "peer" review and an external organization does an external peer review.[91] These reviews often do not take into account the results of an autopsy, if one is performed. Only two of the PCP reviews since 2017 identified concerns. One, written after we started this investigation, noted a need to transfer a resident to a hospital sooner; the other noted only that the PCP was not informed of a call to 911. By contrast, and as discussed above, *see supra* Section IV.B.1.a, the external organization frequently identified deficiencies in the quality of care.

Glenwood has a Mortality Review Committee, consisting of the Superintendent, Director of Quality Management, the Medical Director, and representatives of other departments, that meets to review materials available to it at the time of the meeting. Remarkably, although the external organization frequently identified concerning issues warranting attention, *see supra* Section IV.B.1.a, not once did these meetings produce a recommendation for change or improvement. In fact, most of the time the Committee met to discuss a mortality, it did so without even having the external organization's review. And, once the external review was subsequently received, its recommendations were not shared with the Committee. Instead, the

[91] Due to staffing changes discussed above, *see supra* Section IV.C.2, the then-Medical Director was the only doctor on staff, and had no "peer" at Glenwood to review his care.

then-Superintendent, who had no medical training, and the then-Medical Director discussed them, decided on a plan of action, which typically was to do nothing, and provided no report or documentation back to the Committee.[92] In fact, most members of the Mortality Review Committee were unaware that the external organization was making repeated recommendations about the timeliness of urgent medical care, and unaware that the facility was not taking meaningful responsive action. *See supra* Section IV.B.1.a.

Glenwood and DHS staff did not act on the external organization's recommendations, ostensibly because the recommendations embodied hindsight bias and were late. In fact, far from being biased, the external organization was perhaps overly diplomatic in characterizing the severity of the associated deficiencies in medical care.[93] Further, dismissing the recommendations as tainted by hindsight bias ignores that a purpose of a mortality review is precisely to harness the benefit of hindsight and identify opportunities for improvement. Finally, the external organization's reviews were only "untimely" because, by policy, the Mortality Review Committee did not wait for them. Ultimately, despite these asserted flaws, DHS has acknowledged to us that, of the various internal and external reviews of mortalities, the external organization's reviews were best at identifying areas in need of improvement, but DHS did not effectively use them.

Glenwood's internal mortality reviews are rife with other problems. For example, mortality reviews need to be performed by people with training in quality improvement and with clinical expertise in how to conduct mortality reviews. No one participating in the reviews had that training. Contrary to Glenwood's practice, mortality reviews need to be performed at a time when autopsy results are available, because autopsies are the most likely place to find unexpected information. Also, Glenwood lacks a process for recusal of the Medical Director when the Medical Director's care is under review. In cases where outside recommendations were available to the Committee, if the Committee were to disagree with external recommendations, the reasoning and justification for disagreement must be sound and documented in Committee meeting minutes. We saw no evidence that disagreement was ever discussed, resolved, or documented. In addition, the Committee and reviewers have focused on the wrong question – whether death definitively could have been avoided – rather than the broader question of whether there were deficiencies in care.

Moreover, DHS has taken a hands-off approach to mortalities at Glenwood. In particular, DHS has not routinely reviewed any of the mortality review materials it received. After a marked increase in Glenwood's mortality rates, one DHS staff member attempted to follow up with the then-Superintendent and the then-Medical Director about the disparity in findings between internal and external reviews. They told her that the external organization's

[92] In fact, the then-Medical Director told us that the Superintendent alone decided Glenwood's response to the external reviews and recommendations.

[93] The deficiencies in medical care were also substantiated by our experts' reviews and a review separately conducted by the State.

recommendations were either unnecessary or had been reviewed and addressed, and promised her a plan to address any outstanding recommendations. The plan was quite delayed, and this staff member lacked the clinical resources to determine whether Glenwood's assertion about the need to implement recommendations was reasonable, and lacked the authority to mandate any such implementation. Ultimately, when she raised concerns within DHS that Glenwood was nonresponsive to these issues, DHS took no action to ensure that they were addressed.

D. The State Fails To Provide Effective Oversight of Glenwood

The State has been on notice for years of deficient care and practices exposing Glenwood residents to significant harm and risks of harm. According to press reports, in September 2016, staff not regularly assigned to a home discovered systemic mistreatment of residents there, including staff striking residents on the head with metal spoons and butter knife handles, verbally taunting them, neglecting their personal care, and allowing peer-to-peer aggression.[94] The Department of Inspections and Appeals (DIA)[95] found that some of these violations placed clients in immediate jeopardy,[96] issued a $30,000 fine, placed the facility under a conditional license – one of the most severe penalties – and required that an outside entity analyze the root cause of the failures.

The outside entity, Joint Commission Resources Consulting (JCRC), identified an "environment of distrust and fear of retaliation" at Glenwood. JCRC also identified "key areas of concern related to the culture and environment of safety at Glenwood, which leadership at all levels—governance, senior management, and the organized medical staff—must work together to resolve." JCRC highlighted a number of the systemic deficiencies that exist today, including:

- A perception by staff that investigations are not fair and impartial, which prevented staff from reporting abuse;
- Pervasive disempowerment of staff: "at all levels of authority, no one felt empowered or responsible to question the providers' order to physically restrain[] clients for nonemergent reasons," and staff, including RNs, "felt pressured by senior leaders to complete orders by medical staff despite rational[e] or indications;"
- A failure to ensure that clients were free from unnecessary restraints, and to provide employees adequate training to address aggressive behaviors;

[94] More than a dozen employees were fired or resigned. Six Glenwood employees were arrested, five of whom were convicted or pled guilty to criminal charges.

[95] As discussed below, DIA is the designated state agency responsible for surveying and certifying intermediate care facilities such as Glenwood. It is also responsible for investigating complaints alleging improper care or treatment of residents in licensed and certified entities.

[96] "Immediate jeopardy" means a situation in which immediate corrective action is necessary because the provider's noncompliance with one or more requirements of participation or conditions of participation has caused, or is likely to cause, serious injury, harm, impairment, or death to an individual receiving care in a facility. 42 C.F.R. § 442.2.

- Understaffing and under supervision, leading to frequent mandated overtime, reassignment of staff to unfamiliar homes, and "[s]taff burnout, anxiety, and fear of reprisal"; and
- Failed quality management: the QM Department did not actively monitor incidents of client and staff injuries, data collected from Behavioral Support Plans and Individual Service Plans, HRC Complaints, alleged abuse, and alleged human rights violations to identify potential patterns or trends.

Although JCRC identified numerous issues, DHS officials focused on one: the failure by staff to report abuse for fear of retaliation.[97] DHS's response was to increase supervision of direct care staff in the houses and retrain all staff at the facility about the expectations to report abuse and neglect and that retaliation will not be tolerated.

In the years that followed the JCRC report, state officials received an unusual and alarming number of complaints regarding worsening conditions at Glenwood. Time after time, the State failed to thoroughly investigate the concerns – often taking at face value the response from the facility itself, and dismissing the complaints as a symptom of staff dissatisfaction and resistance to change. Yet, as discussed below, the State did not take any action to address the dissatisfaction and resistance to change it blamed for the volume of complaints.

For instance, in February 2018, multiple staff contacted DHS officials to express significant concerns about Glenwood. An experienced Glenwood manager wrote to DHS Director Foxhoven alerting him to "draconian changes being made" at the facility, and a "hostile work environment" that suppressed dissent. The email details numerous changes that had taken place since Dr. Rea became Superintendent, including: the elimination of policies that were created to safeguard residents; changes to restraint policies and the potential introduction of mechanical restraints; the firing or suspension of staff under questionable circumstances; and reductions in the compliance, training, and reporting functions handled by Glenwood's Quality Management Department, with those responsibilities shifted to people with "very little or no experience in such matters." This manager warned of "grave risk" to client welfare and said "[t]he end result of Mr. [sic] Rea's actions will be a dangerous environment for the clients and staff, a hostile work environment and eventually heavy fines from oversight agencies." The manager also asserted that MHDS Division Administrator Mr. Shults was covering up Dr. Rea's actions and demonstrated a "lack of oversight and willingness to take action."

Director Foxhoven responded to the complainant to say that he would look into the issues. When interviewed and shown the email, Mr. Foxhoven said that he did not recall the communication. However, he expected he would have shown the email to Mr. Shults and would

[97] DHS was also aware of weaknesses in the Behavioral Services Department and Medical Department at this time. These concerns were identified by the Interim Superintendent and conveyed to Central Office leadership. Line staff's inability to approach leadership, and communication breakdowns between line staff and medical staff, were also apparent. But State officials report that these issues were overshadowed by the immediate focus on failures to report abuse and neglect.

have deferred to an investigation by the Department of Administrative Services (DAS) – a separate Department of the State that is responsible, among other things, for investigating violations of State employment policies and advising state agencies on personnel issues – because the email referenced a pending grievance with that Department. Neither response would have been reasonable under the circumstances, where the email raised issues well beyond DAS's investigative authority and implicated Mr. Shults as part of the problem.[98]

Also in February 2018, one of the facility's physicians contacted Director Foxhoven by phone and email, stating that recent management of medical care at the facility had been "egregiously careless." He had previously expressed his concerns by joining with other Glenwood PCPs in a vote of no confidence regarding the then-Medical Director, and he resigned in March 2018. His concerns were dismissed by DHS as those of a dissatisfied former employee, and were not reconsidered even when other staff later expressed concerns with medical care.

Again, in February 2018, another experienced manager wrote to Director Foxhoven saying that staff were demoralized and that multiple staff members were resigning because "the stress level is so high." She also identified concerns that the Superintendent and Administrator of Nursing were making medical decisions which neither of them were competent to decide. Director Foxhoven replied by promising action. However, when interviewed, he could not recall what specific actions he had planned to take, and we have found no evidence that any action was taken at the time. In July 2018, the same manager wrote to Director Foxhoven, noting that "[r]etribution here will be severe if I am found out" and that many other concerned staff were too afraid of retaliation to speak out. The email included an itemized list of alarming developments:

- A severe reduction in the staffing of the medical Department and decline in the quality of care.
- Increased hydration for a "trial group" of nine medically fragile individuals, all but one of whom were tube fed, to "dangerously high levels," purportedly to reduce the risk of pneumonia.
- The implementation of supine restraints that were not previously allowed in the facility, the use of restraints with residents who did not previously need them, and the intention to use mechanical restraints with at least one person.

[98] DAS's Employee Relations Bureau investigates violations of three State policies related to sexual harassment, workplace violence, and anti-discrimination. Allegations that fall outside of these three policies, or involve a client, are referred back to the DHS Director and DHS's Human Resources designee. Employees within the Bureau stated that do not have the authority to investigate retaliation more broadly. Moreover, the grievance this employee had filed with DAS related to a narrow dispute regarding Glenwood leadership's inappropriate treatment of this complainant. The attorney who handled the investigation concluded that the behavior, while inappropriate, did not violate the workplace violence policy DAS was tasked with enforcing. DAS in fact referred the grievance to Mr. Foxhoven, as Director of DHS, to address the inappropriate behavior. The original complainant never heard back from anyone at DHS.

- A preoccupation with conducting research.

This email provided DHS with a roadmap of allegations of serious harm to Glenwood residents that our investigation has confirmed to be largely accurate, but DHS dismissed it. For example, as to overhydration, Director Foxhoven merely confirmed that the orders were made by a doctor.[99] He added that the parents and guardians seemed satisfied with the medical care. Ultimately, despite numerous complaints about medical care in the facility, he relied on that same facility's doctor to make decisions. Further, he did not "ever even consider[]" having an external physician or organization look at medical care at Glenwood.

Other DHS staff reported that they were unaware of this email until July 2019, when it was discovered in the process of responding to an open records request. At that time the only review of these allegations was performed by a Central Office official who had no clinical background and no assistance from anyone with clinical expertise.

A third Glenwood manager, who had been working at the facility for decades, also reported concerns to Director Foxhoven in early 2018 regarding the facility's medical care and the elimination of staff. She told us that this was the first time she had jumped the chain of command to elevate concerns in this manner and that she believes the number of people contacting him was unprecedented.

Direct care workers also raised concerns to DHS. In May 2019, a direct care worker emailed Director Foxhoven, saying changes in the way residents were treated had caused them to "act[] out behaviorally in ways we haven't seen but upon entry of the facility years and years ago . . . . Our concerns are mainly being ignored and we are being retaliated against for caring about our residents[']well being." Director Foxhoven and Mr. Shults told us that they assumed that this employee was upset about a change in her shift assignment. No one in Central Office investigated these allegations.

Director Foxhoven acknowledged to us that he received "way more complaints" from staff at Glenwood than from staff at any other DHS facility. He dismissed these complaints because Glenwood was viewed as a troubled facility where there was "a lot of dissatisfaction for years."

These complaints were accompanied by other serious warning signs that should have alerted DHS to the risks within Glenwood. Since 2017, Glenwood has received frequent citations from DIA. DIA's citations, issued almost monthly, reflect a pattern of persistent concerns about the facility's ability to ensure Glenwood residents' basic health, safety, and well-being, and a failure on the part of the State to remediate those concerns. DIA found condition-

[99] Director Foxhoven was also provided data at some point showing the rates of pneumonia had declined. As discussed above, *see supra* Section IV.A.1.b, rates of pneumonia had not declined, either in July 2018 at the time of this email or in February 2019 when DHS represented otherwise to the legislature. But neither Director Foxhoven nor anyone else at DHS took steps to verify the accuracy of data they received from Glenwood. Moreover, DHS's focus exclusively on one manipulated data point ignored the other harms that individuals were experiencing, or at risk of experiencing, as a result of forced overhydration.

level deficiencies in 2017 and 2019,[100] and repeated standard-level deficiencies each year related to conditions that directly affect client outcomes. This included deficiencies related to Client Protections, Active Treatment, Health Services, and Facility Staffing. Return visits frequently result in continued findings of noncompliance.[101] Despite this pattern of findings, DIA's almost constant presence at the facility, and the fact that DHS leadership was aware that Glenwood was cited more often than other facilities, DHS was not prompted to take meaningful or effective action.[102]

In addition, in April 2019, the Iowa Occupational Safety and Health Administration (IOSHA) proposed fining Glenwood almost $60,000, one of the highest penalties in the state that year, for 16 "serious" worker safety violations. The state employees' union said the incidents stemmed from chronic staff shortages, an assertion DHS denied. In August 2019, IOSHA informed DHS that it continued to receive complaints from staff regarding injuries they incurred from individuals at the facility. IOSHA also recommended that DHS evaluate whether the facility was able to serve some clients.

Glenwood employees also shared concerns outside DHS, including with legislators, DIA, DAS, the Iowa Board of Medicine, and the Parents and Guardians Association. Ultimately, the response of these outside parties was hamstrung by DHS providing inadequate or misleading information and by inherent limitations in their access, resources, and authority. In February 2019, State Senators and Representatives posed questions to DHS about: the unusual number of deaths at the facility; inappropriate changes in seizure medications; the perfect care index; concerns about the potential implementation of mechanical restraints and the new CIT approach to restraints in the facility; allegations that human subjects research was being inappropriately conducted on GRC residents; allegations that staff were instructed to falsify records; high rates of staff turnover; and other concerns related to staff morale.

DHS relied almost entirely on Glenwood staff to prepare a response, and no one in Central Office verified that the information gathered by Glenwood was accurate before sharing it

[100] The regulations set forth eight conditions of participation for ICFs, and standards within each condition. 42 C.F.R. §§ 483.400-480. Surveyors may find the ICF is out of compliance with a particular standard (a standard-level deficiency) or that an entity is out of compliance with an entire Condition of Participation (a more severe condition-level deficiency).

[101] For example, a DIA report of Glenwood's compliance history as of March 2020 shows that Glenwood remains out of compliance with the findings of a November 2018 investigation, which found a failure to ensure alleged mistreatment, neglect, abuse, and injuries of an unknown source are thoroughly investigated, and a failure to ensure needed interventions and services are provided in accordance with individual program plans.

[102] We emphasize that DHS – not DIA – bears the ultimate responsibility for the facility's systemic policies and practices. DIA's more narrow regulatory function, while essential, does not guarantee constitutionally adequate care. *United States v. Tenn.*, 798 F. Supp. 483, 489 (W.D. Tenn. 1992) (citing *Lelsz v. Kavanagh*, 673 F. Supp. 828, 841 (N.D. Tex. 1987)). *See also Wyatt ex rel. Rawlins v. Rogers*, 985 F. Supp. 1356, 1431 (M.D. Ala. 1997) (Medicaid certification "is not the equivalent of substantial compliance with . . . constitutional minimum standards."). Nevertheless, the pattern of regulatory citations was compelling evidence of the State's failure to provide reasonable care and safety, which should have prompted DHS to evaluate and address the root of the issue.

with legislators. That information was misleading, at best, as discussed above. *See supra* Section IV.A.1.b.

Just months after receiving questions by legislators about the number of deaths at the facility, Glenwood's mortality rate received significant press attention. *See supra* Section IV.B.1.a. The press also highlighted the 2018 resignation of the physician, discussed above, who wrote to Director Foxhoven in 2018 to say that "[l]eadership at the facility has gutted the medical staff in such a way that they have placed our residents, the state's most vulnerable adults, at risk. . . . Practicing here in the present status of affairs is dangerous, both personally and professionally."

Even in the face of attention from the press and from legislators about the rising mortality rate, DHS did not undertake an external clinical review of the medical care provided at Glenwood, or conduct any meaningful evaluation of clinical practice, until after we commenced this investigation. In fact, although mortality reviews conducted by an external organization identified consistent areas of concern, *see supra* Section IV.B.1.a, the former DHS Director was unaware of any adverse results or recommended changes. Once again, he told us that he assumed that if there were an issue, he would be made aware of it. But he did not have a system in place to ensure he would in fact be alerted to an issue like concerns about mortalities. Those in Central Office who knew of the external recommendations failed to ensure that they were implemented, and apparently failed to share these issues with the Director. *See supra* Section IV.C.2.a. Similarly, although reports of retaliation within the facility date back to at least 2017, DHS's Central Office never investigated.

A number of structural deficiencies prevented DHS from engaging in proactive oversight and supervision of Glenwood in a number of fundamental areas, including policy development and implementation, quality assurance and improvement systems, evaluation and supervision of facility personnel, maintenance of adequate staffing and facility resources, and organizational culture.

First, Central Office staff do not oversee and report on facility operations and outcomes in a reliable manner. Rather, DHS leadership delegated to the Office of Facility Support (OFS) staff – viewed by Central Office as the "eyes and ears" within the facilities – almost all monitoring and oversight of Glenwood, even though OFS staff do not have the necessary subject matter expertise or the authority needed to act in leadership's place. Described as liaisons or advocates for the facilities, they are not in a position to enforce expectations, or to direct facility staff to take action. The staff member assigned to Glenwood told us that superintendents do not feel they need to report or respond to her or other OFS staff. They report to the Division Administrator, as does she.

Further, DHS lacks the resources to oversee Glenwood (and its other five facilities) in a reliable way. In particular, the lack of clinical expertise prevents any meaningful DHS supervision of clinical practice at Glenwood. For instance, there is no physician in place to supervise the performance of Glenwood's Medical Director, so that supervision is left to the non-

physician Superintendent. DHS officials agree that Central Office needs access to a physician to assist with this oversight.

Additionally, DHS does not have any standard quality indicators for facilities or mechanisms for routine reporting on such indicators, which would allow people at multiple levels to monitor system performance. More broadly, state officials acknowledge the responsibility for developing, implementing, and monitoring adherence to policies and procedures at the agency level, and admit that Central Office currently lacks the capacity to provide such proactive oversight and auditing.[103] DHS recognizes the need for additional staff and skillsets, and for a continuous quality improvement office reporting directly to leadership, to set and measure goals, report on quality indicators, investigate potential problems, and prevent backsliding.

Since the onset of our investigation, the State has taken an encouraging and forthright approach in acknowledging many of these issues – although these issues persist today. In addition, the State has taken preliminary steps to address some of the deficiencies we identify. With respect to Central Office's oversight deficiencies, this includes seeking to fill a project manager position, splitting the MHDS Division Administrator position in two, and assigning responsibility for all work related to community integration to the new Administrator. The State is also considering whether to hire an MHDS Medical Director. These are positive steps that, if taken, will assist DHS in exercising adequate oversight of Glenwood. Set forth below are additional measures that the State must undertake to correct, and minimize the reoccurrence of, the harms and serious risks of harm to Glenwood's residents described in this Notice.

V. MINIMUM REMEDIAL MEASURES

To remedy the violations identified in this Notice, we recommend that Iowa implement, at a minimum, the remedial measures listed below. In listing these remedies, we note that over the course of our investigation Iowa has been making changes to its personnel, policies, and procedures, to begin to mitigate some of the violations identified in this Notice.

A. Protecting Residents from Uncontrolled Research

The State should ensure:

1. Ongoing independent review of the use, or proposed use, of any interventions having an objective to develop or contribute to generalizable knowledge, i.e., research;
2. Residents, their guardians, or both, understand the risks and benefits of the research and provide informed consent before those residents are subjected to research;

[103] These deficiencies were underscored in the Recommendations for Remediation issued by the State's Expert in May 2020, which called, among other things, for DHS to immediately provide clear expectations for the Superintendent and leadership team, and establish an "effective oversight system at DHS to monitor compliance to those expectations and provide feedback." Recommendations for Remediation at 1.

3. Appropriate safeguards are in place to minimize risk associated with proposed or ongoing research, including monitoring for negative impacts of research and terminating research when appropriate; and

4. Staff receive adequate competency-based training on protecting the rights and safety of research subjects.

B. Providing Adequate Physical Health Care

The State should ensure that Glenwood residents receive routine, preventative, and emergency medical care consistent with generally accepted professional standards. Specifically, the State should:

1. Ensure that all clinical staff are appropriately trained, and have received and continue to receive appropriate professional development such that they are competent in working with and providing clinical services to individuals with IDD;

2. Ensure that all residents who experience acute changes of condition receive timely and appropriate nursing and medical responses, including where necessary prompt transfer to higher levels of care (e.g., hospitals or emergency rooms);

3. Ensure that laboratory results are appropriately and timely reviewed, including taking appropriate action and documenting the reasons for action and inaction, pursuant to appropriate policies, practices, and procedures;

4. Implement appropriate and effective use of consultations with specialists;

5. Implement appropriate interdisciplinary information sharing, notification, and collaboration from, with, between, and among direct care staff, clinical staff, and consultant clinicians, and appropriate resulting interdisciplinary action, as needed;

6. Ensure that medications are prescribed in a safe and appropriate manner;

7. Ensure safe and accurate administration of medication, including appropriate: reporting of medication variances and potential variances, auditing to identify unreported medication variances, investigation of medication variances, and implementation of remedial and preventative measures, as warranted; and

8. Ensure that documentation in individuals' health records is thorough and accurate.

C. Providing Adequate Behavioral Health Care

The State should ensure that Glenwood residents receive behavioral supports and services consistent with generally accepted professional standards. Specifically, the State should:

1. Retain a sufficient number of psychology staff who are trained and certified in applied behavioral analysis to meet the behavioral health needs of Glenwood's residents;

2. Ensure that all psychology staff are competent to work with and provide behavioral services to individuals with IDD with challenging behaviors;

3. Ensure that all staff responsible for training and monitoring implementation of behavioral programming are themselves competent to do so and monitored by the psychologists;

4. Ensure that all staff responsible for implementing behavioral programming are competent in applying general behavioral health concepts and in implementing the individual plans of the residents for whom they are responsible;

5. Ensure that reliable, complete, and substantiated behavioral health assessments are completed for all Glenwood residents regularly and as often as needed, and that behavioral health data are adequately and accurately collected;

6. Ensure that adequate behavior support plans are completed, consistently implemented, and monitored for all residents of Glenwood who need one;

7. Ensure that each resident at Glenwood receives continuous, aggressive, and consistent implementation of individualized, meaningful, and appropriate programming, including the regular opportunity to engage in community-based activities;

8. Regularly assess the mental health needs of Glenwood residents and ensure that needed counseling and other therapeutic interventions are available and provided to residents;

9. Ensure that restraints, seclusion, and other restrictive interventions are utilized only after less intrusive interventions have been attempted and failed or are otherwise insufficient and with appropriate safeguards, and ensure that after repeated instances of restraint or an increasing trend in restraint data, the IDT will examine and refine the individual's behavioral programming using data-based decision-making; and

10. Ensure that the Psychology Department is involved in the selection of, and trains staff in, any crisis management systems used by Glenwood.

D. Providing Safety, Quality Assurance, and Quality Improvement

The State should:

1. Develop and maintain an effective accountability system for Glenwood. This should include:

    a. Developing effective mechanisms that (1) enable staff to raise issues regarding resident well-being and employee relations to supervisors, the Quality Management Department, Glenwood leadership, DHS Central Office, and external oversight bodies, without experiencing retaliation; (2) cause those issues to be reliably investigated and addressed; and (3) where feasible, for issues raised within Glenwood or to DHS, have the entity receiving the complaint or concern provide a substantive response regarding its resolution to the staff who raised it;

    b. Developing effective mechanisms for identifying, tracking, and addressing trends regarding resident well-being and employee relations;

c. Conducting ongoing training, observation, and coaching of Glenwood leadership to ensure the initiatives are carried out;

d. Holding accountable all Glenwood staff and supervisors, and all DHS staff with oversight responsibility for Glenwood, for the initiatives' implementation;

2. Maintain a Quality Management system (including both Quality Assurance and Quality Improvement) that:

a. Establishes, trains on, and enforces standards, policies, and practices promoting health and safety;

b. Develops sufficient, reliable measures for resident outcomes and service processes, corresponding goals and timelines for expected positive outcomes and processes, and identified triggers for negative outcomes, changes in health status, and deficient processes;

c. Obtains, integrates, and analyzes sufficient valid data to track and trend the measures and triggers described above at the individual, residential/day setting, and facility-wide levels;

d. Produces regular, reliable Quality Management reporting on the defined measures, and triggers described above;

e. Identifies, assesses, and appropriately responds to significant incidents, including by conducting effective root cause analyses of very serious incidents and reliable interdisciplinary mortality reviews of unexpected deaths;

f. Identifies trends at the individual, residential/day setting, and facility-wide levels, in light of defined outcome and process measures and triggers; and

g. Remediates negative trends and builds on positive trends;

3. Maintain competent, appropriately trained, and credentialed staff and facility leadership in sufficient numbers and with appropriately aligned responsibilities and workloads to serve Glenwood's residents in an appropriate manner;

4. Conduct a comprehensive review of the adequacy and propriety of Glenwood's policies, practices, procedures, protocols, rules, or similar documents, and their implementation, and take all necessary steps to remedy any insufficiencies or improprieties; and

5. Develop, implement, and enforce policies, practices, and procedures necessary to implement all remedial measures.

E. Ensuring Appropriate Oversight of Glenwood

The State should:

1. Establish clear roles, responsibilities, and expectations for the Glenwood Superintendent and managerial staff, and for all DHS Central Office personnel who conduct facility oversight;
2. Ensure DHS Central Office staff with the requisite expertise conduct routine, comprehensive, and reliable evaluations of Glenwood performance and compliance with policies and procedures;
3. Ensure DHS Central Office is notified of, and has an opportunity to countermand, changes in policies regarding the care of Glenwood residents;
4. Ensure DHS Central Office review and approval of the hiring, firing, and discipline of Glenwood leadership staff, including department heads, assistant superintendents, and treatment program managers;
5. Ensure routine, comprehensive performance evaluations of Glenwood's superintendent and leadership staff are conducted by someone with the requisite expertise, with external peer reviews of clinicians;
6. Ensure the Central Office leadership receives routine, accurately validated Quality Management reporting regarding the measures, goals, and triggers described above, and related trends; notification of complaints regarding resident well-being and employee relations, and related trends; and other relevant reporting regarding Glenwood;
7. Establish regular, reliable public reporting and periodic independent assessments to validate Glenwood reports and evaluate performance in at least the following areas: all physical and behavioral health services; client rights and protections, including protections against unnecessary restraints and restrictive procedures; individual service planning; admission and discharge processes; quality management functions; and risk and incident management;
8. Ensure DHS Central Office has effective processes for identifying, directing, and monitoring the implementation of needed corrective actions and performance improvement initiatives at Glenwood;
9. Ensure effective communication and collaboration with other agencies responsible for systemic oversight of Glenwood, including the Department of Inspections and Appeals, and the Protection and Advocacy agency; and
10. Ensure sufficient expertise and capacity in DHS Central Office to conduct the activities above.

VI. CONCLUSION

We appreciate Iowa's cooperation during the investigation. We recognize the collaborative spirit that DHS and the interim leadership of Glenwood brought to the investigation, and that DHS has provided timely information about steps that it was taking to attempt to mitigate the deficiencies described in this Notice. We also thank the residents of Glenwood for welcoming us into their homes.

We have reasonable cause to believe that the State has engaged in a pattern or practice of resistance to rights protected by the Fourteenth Amendment because it subjects residents of Glenwood to unreasonable harm and risk of harm by exposing residents to uncontrolled and unsupervised experimentation, inadequate physical and behavioral healthcare, and inadequate protections from harm. We look forward to working cooperatively with the State to ensure that these violations are remedied.

Attachment C

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF IOWA
CENTRAL DIVISION

UNITED STATES OF AMERICA, Plaintiff, v. STATE OF IOWA, Defendant.	Civil No.

SETTLEMENT AGREEMENT and CONSENT DECREE
TO RESOLVE THE DEPARTMENT OF JUSTICE'S INVESTIGATION OF
GLENWOOD RESOURCE CENTER CONDITIONS

I. Introduction

1. In 2019, the United States initiated an investigation pursuant to the Civil Rights of Institutionalized Persons Act (CRIPA), 42 U.S.C. § 1997, and Title II of the Americans with Disabilities Act, 42 U.S.C. § 12101 *et seq*. (ADA). The investigation focused on:

    a. Whether the State of Iowa ("State") engages in a pattern or practice of violating the federal rights of residents of Glenwood Resource Center ("Glenwood" or GRC), who have intellectual or developmental disabilities (IDD). The investigation looked at whether the State places residents at serious risk of harm by subjecting them to: (1) harmful and uncontrolled human subject experiments; (2) inadequate medical and nursing care, physical and nutritional management, and behavioral health care; (3) needless and harmful restraint practices; or (4) incidents causing needless physical injury;

    b. Whether the State violates the rights of residents of Glenwood and Woodward Resource Center ("Woodward" or WRC) (collectively, "the Resource Centers") to receive services in the most integrated setting appropriate under the ADA.

2. On December 22, 2020, the United States issued a CRIPA Notice to the State, concluding that there is reasonable cause to believe that the State violates the Fourteenth Amendment of the U.S. Constitution by subjecting Glenwood's residents to unreasonable harm and risk of harm because it exposes them to: uncontrolled and unsupervised experimentation; inadequate physical and behavioral healthcare; and inadequate protections from harm, including deficient safety and oversight mechanisms. The United States concluded that these violations form a pattern or practice of resistance to the full enjoyment of rights protected by the Fourteenth Amendment.

3. On December 8, 2021, the United States issued a second Notice to the State, concluding that that there is reasonable cause to believe the State violates Title II of the ADA by failing to provide services to qualified people with IDD in the most integrated setting appropriate to their needs. This conclusion applies to individuals residing in the State Resource Centers and those at serious risk of institutionalization. The investigation found that the State plans, administers, and funds its public healthcare service system in a manner that unnecessarily segregates people with IDD in Resource Centers, and almost certainly many other institutions, rather than providing these services where people live, in their community.

4. The State has decided to close Glenwood in approximately two years. The State and the United States (collectively, "the Parties") are committed to remedying the conditions at Glenwood identified in the December 22, 2020 Notice while Glenwood remains open, and the conditions identified in the December 8, 2021, Notice. The purpose of this Agreement is to ensure that the State meets the Fourteenth Amendment rights of individuals residing at Glenwood to adequate care and safety, and the rights of all individuals in Target Population under Title II of the Americans with Disabilities Act.

5. In order to resolve the issues pending between the Parties without the expense, risks, delays, and uncertainties of litigation, the Parties agree to the terms of this Agreement as stated below. This Agreement resolves the United States' investigation of the conditions at Glenwood. This Agreement is also the first part of a phased effort to resolve both investigations. The Parties agree to negotiate in good faith regarding additions to this Agreement to address the December 8, 2021, Notice as well. The parties acknowledge that circumstances may change given the length of the Agreement. Both parties agree to reasonably, and in good faith, negotiate amendments to this decree upon request.

6. This Agreement is enforceable only by the Parties and the Court. No person or entity is intended to be a third-party beneficiary of the provisions of this Agreement for purposes of any civil, criminal, or administrative action. Accordingly, no person or entity may assert any claim or right as a beneficiary or protected person under this Agreement.

II. Target Population

7. The Target Population of this Agreement shall include people with IDD who:

    a. Live at Glenwood; or

    b. Lived at Glenwood during the course of this Agreement, or within 365 days prior to the Effective Date of this Agreement.

III. Definitions

8. An **Administrator on Duty** means a designated member of GRC Leadership with on-call availability and decision-making responsibility at a particular time.

9. An **Authorized Representative** means a person who is authorized by law to act on behalf of an individual.

10. A **Behavior Support Plan (BSP)** is a comprehensive, individualized plan, developed consistent with current, generally accepted professional standards. A BSP contains intervention strategies designed to modify the environment to minimize antecedents of problematic behaviors and maximize antecedents of positive behaviors, teach or increase adaptive skills, and reduce or prevent the occurrence of target behaviors. It does so through interventions that build on the individual's strengths and preferences and that exclude aversive or punishment contingencies. The BSP is based on an accurate, comprehensive assessment of target behaviors, including an assessment of the antecedents and consequences of those behaviors, that integrates assessment information from psychiatric, medical, and other disciplines. The BSP is a component of the Individual Support Plan (ISP) and includes:

    a. The objective delineation of target behaviors, including baseline levels of behavior;

b. Training for the individual to acquire or increase replacement behaviors that are selected on the basis of the assessment in Paragraph 105, and specific implementation procedures for how staff will provide such training; and

c. Target behavior reduction strategies, based on the assessment in Paragraph 105, and specific implementation procedures for such strategies.

11. A **Behavioral Health Professional** has a minimum of a Master's degree, and a certification or license, in psychology, behavioral analysis, or social work, and has experience working with adults with IDD who have significant challenging behaviors and the co-occurrence of mental health issues.

12. A **Case Manager** is an individual with experience in coordinating or providing community-based services and person-centered planning to members of the Target Population, as defined in Paragraph 7. Case Managers must be trained and knowledgeable about the resources, supports, services, and opportunities available in the state and be independent of Community-Based Service providers who may provide direct services to their assigned clients, and of the Resource Centers.

13. **Community-Based Services** are person-centered services delivered in an integrated and coordinated manner to members of the Target Population provided as necessary to support individuals to live in the community and avoid unnecessary institutionalization.

14. A **Community Provider** is an individual or entity who provides Community-Based Services, paid in whole or in part by the State, or through a managed care arrangement, to a member of the Target Population.

15. **Competency-Based Training** is the provision of knowledge and skills sufficient to enable the trained person to meet specified standards of performance as validated through that person's demonstration of such knowledge or skills in a context similar to one in which such knowledge or skills would be required.

16. A **Developmental Disability** means a severe, chronic disability of an individual that: (1) is attributable to a mental or physical impairment or combination of mental and physical impairments; (2) is manifested before the individual attains age 22; (3) is likely to continue indefinitely; (4) results in substantial functional limitations in three or more of the following areas of major life activity: (a) self-care; (b) receptive and expressive language; (c) learning; (d) mobility; (e) self-direction; (f) capacity for independent living; (g) economic self-sufficiency; and (5) reflects the individual's need for a combination and sequence of special, interdisciplinary, or generic services, individualized supports, or other forms of assistance that are of lifelong or extended duration and are individually planned and coordinated. Developmental disability is diagnosed by a qualified professional. 42 U.S.C. § 15002.

17. **HHS** means the Iowa Health and Human Services department (HHS), and any past or future departments with the same functions, including the Department of Human Services, which merged into HHS effective August 30, 2022.

18. **HHS Central Office** means the Director of HHS and subsidiary Divisions including the Divisions of Disability and Behavioral Health; Medicaid; Strategic Operations; State-Operated Facilities; and any other past, current, or future Bureau, Division, or intra-departmental support within HHS that is responsible for overseeing GRC staff or operations or community-based services and integration for people with IDD.

19. A **Discharge Plan** is a person-centered plan that identifies supports and services enabling a person to move to the most integrated setting appropriate to the person's needs and that accounts for the person's preferences.

20. The **Effective Date** is the date on which the Court enters this Agreement as an order of the Court.

21. **GRC Leadership** are GRC staff who are responsible for supervising departments, including the Superintendent, department heads, and assistant superintendents.

22. The **Human Rights Committee** is a group that includes at least one Behavioral Health Professional, at least one Treatment Program Manager, at least one Residential Treatment Worker, at least two residents of GRC, at least one person not employed or compensated by the State who is the family member of a resident at GRC, at least one community member who has knowledge of community-based behavioral services and is not employed or compensated by the State, and at least one advocate or representative of the disability community or of individuals with disabilities who is not employed or compensated by the State. GRC staff may never be the majority of Human Rights Committee members. The Human Rights Committee reviews recommended programmatic restrictive interventions and environmental restrictions, approves or denies approval of those interventions, and monitors the implementation of those interventions; reviews grievances or allegations of rights violations; makes recommendations for program improvement; and maintains a record of the decisions of the Committee.

23. **IDD** for purposes of this Agreement means an intellectual disability, a developmental disability, or both.

24. An **Individual Support Plan** (ISP) is a document that sets out, in an integrated and coherent manner, all of the protections, supports, and services to be provided to the individual. An ISP is developed by the individual's Interdisciplinary Team through comprehensive assessments of the individual; reflects, to the fullest extent practicable, the individual's preferences, strengths, needs, informed choices, and desires; and includes methods to track and document progress toward identified goals and objectives.

25. An **Institutional Review Board** is an entity that ensures complete and adequate review of research activities, consistent with the requirements of 45 C.F.R. §§ 46.107 to 115. For purposes of this agreement, the Institutional Review Board includes at least one member external to the HHS.

26. An **Intellectual Disability** or **ID** means a disability characterized by significant limitations both in intellectual functioning (reasoning, learning, problem solving) and in adaptive

behavior, which covers a range of everyday social and practical skills. This disability originates before the age of 18 and is diagnosed by a qualified professional. An intellectual disability is a type of developmental disability.

27. An **Interdisciplinary Team** (IDT) is a collection of people with varied professional backgrounds (including people from all disciplines relevant to a particular individual's care needs, that individual, and people who support the individual and know his or her strengths, preferences, and needs) who develop and implement an integrated plan of care to meet the individual's need for services. It includes the individual, the Authorized Representative (if any), the assigned case manager, and people whom the individual has freely chosen or requested to participate (including but not limited to family members and close friends).

28. **Medicaid Managed Care Organization** (MCO) is a private entity that contracts with the State to provide core benefits and services to Iowa Medicaid MCO program enrollees in exchange for a monthly prepaid capitated amount.

29. **Money Follows the Person** (MFP) is Iowa's initiative to assist people in transitioning from institutions to community homes of their choice, funded through a federal Demonstration grant.

30. **Not Compliant** indicates that most or all of the components of a provision of this Agreement have not yet been met.

31. **Partially Compliant** means the State has made tangible progress in achieving substantial compliance with key components of a provision of this Agreement, but significant work remains.

32. **Person-centered Planning** is a process driven by the individual that identifies supports and services that are necessary to meet the individual's needs in the most integrated setting and accounts for the individual's preferences. The individual directs the process to the maximum extent possible and is provided sufficient information and support to make informed choices and decisions. The process is timely and occurs at times and locations convenient to the individual; reflects the cultural and linguistic considerations of the individual; provides information in plain language and in a manner that is accessible to the individual; and includes strategies for resolving conflict or disagreement that arises in the planning process.

33. **Quality Management** is a formalized quality assurance and continuous quality improvement system that ensures that all activities and services for individuals in the Target Population are of good quality, meet individuals' needs, and help individuals achieve positive outcomes, including avoidance of harms, increased community integration, independence, and self-determination in all life domains (e.g., community living, employment, education, recreation, healthcare, and relationships), and ensures that appropriate services are available and accessible. A quality management system includes the determination of policies and procedures regarding quality management, and the

creation and implementation of quality planning and assurance, and quality control and quality improvement activities.

34. **Research** is a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. This includes any activity that involves the introduction of an untested clinical intervention when any purpose of such introduction is to collect information about patient outcomes for the purpose of establishing evidence to determine how well the intervention achieves its intended result, even if there are additional purposes for such introduction.

35. **Restraints** include procedures within one of the following categories:

    a. A **Chemical Restraint** is any drug that: is administered to manage an individual's behavior in a way that reduces the safety risk to the resident or others; has the temporary effect of restricting the individual's freedom of movement; and is not a standard treatment for the individual's medical or psychiatric condition.

    b. A **Mechanical Restraint** is any device attached or adjacent to an individual's body that he or she cannot easily remove that restricts freedom of movement or normal access to his or her body. The term does not include mechanical supports used to achieve functional body position or proper balance.

    c. A **Medical Restraint** is a health-related protection that is prescribed by a physician and that is necessary for the conduct of a specific medical (including dental) procedure, or only is necessary for protection during the time that a medical or dental condition exists, to prevent a person from inhibiting or undoing medical or dental treatment.

    d. A **Physical Restraint** is any manual method that restricts freedom of movement or normal access to one's body, contingent on maladaptive behavior, including hand or arm holding to escort an individual over his or her resistance to being escorted. Physical restraint does not include brief, limited, and isolated use of: physical guidance and/or prompting techniques that are used to redirect an individual or assist, support, or protect the individual during a functional therapeutic or physical exercise activity; response blocking and brief redirection used to interrupt an individual's limbs or body without the use of force so that the occurrence of maladaptive behavior is prevented; holding, without the use of pressure or force, to calm or comfort, or hand holding to escort from one area to another; and response interruption used to interrupt an individual's behavior using approved techniques.

36. A **Restrictive Intervention** is an action by GRC to limit or restrict an individual's movement; access to other individuals, locations, preferred items, or activities; or privacy or autonomy.

37. **Seclusion** is isolating an individual from others to interrupt and intervene with a target behavior. It includes placing an individual in their own house or room for the purposes of behavior management or for the protection of the individual or others, and restricting the individual's ability to exit.

38. **Substantially Compliant** means the State has met or achieved all or nearly all the components of a particular provision of this Agreement.

39. A **Transition Plan** is the plan, developed when an appropriate discharge setting has been identified for an individual, that specifies the actions that need to be taken by the Resource Center, the receiving provider, the MCO, the Money Follows the Person Program, and any other involved entities, to accomplish the discharge and assure success in the new setting. It identifies all needed supports, protections, and services, who shall provide them, and when, to ensure successful transition to the new living environment, including what is most important to the individual as it relates to community placement.

40. **Well-being** means a person's general positive status in the areas of cognitive, behavioral, psychological, emotional, social, and physical health.

IV. Substantive Provisions

A. Research

41. No GRC resident shall be subjected to any Research unless:

    a. The resident has provided written Informed Consent for such Research. If the resident has a guardian, written Informed Consent must be obtained from the guardian, and the resident must assent to participate in the Research;

    b. The Research has been independently reviewed and is under active approval by an Institutional Review Board.

42. GRC, subject to confirmation by an Institutional Review Board, will ensure that any risks associated with Research are minimized and reasonable.

43. GRC, subject to confirmation by an Institutional Review Board, will ensure that residents subject to Research are monitored by an individual with experience in conducting research to ensure safety while the Research is ongoing, and that Research is terminated if it poses an undue risk to resident safety. All residents subject to Research will be free to cease participation in such Research at any time and for any reason without perceived or actual repercussion or other negative impact to the resident.

44. The State shall implement and enforce policies and procedures concerning Research that are consistent with the provisions of this Section and with current, generally accepted professional standards regarding the conduct of research.

45. All staff involved in conducting research shall demonstrate competence in the responsible conduct of research.

46. The State shall conduct effective oversight throughout the implementation of this Agreement to detect noncompliance with the requirements of Section IV.A.

47. For purposes of this Section, Informed Consent is consent that meets the requirements set forth in 45 C.F.R. §§ 46.116(a), (b), and (c).

B. Integrated Interdisciplinary Care and Services

48. Every GRC resident shall receive, consistent with current, generally accepted professional standards of care: person-centered planning, and individualized protections, services, supports, and treatments.

49. Every resident's protections, planning, services, supports, and treatments shall be documented in the ISP, which shall be updated annually, and when the resident's service needs and preferences change. Each resident shall have the opportunity to participate in service planning meetings about their services and will have the opportunity to provide input to each of their service plans and/or revision of that plan. If a resident has a guardian, these same participation and input opportunities will be offered to the guardian. GRC will include a reason for non-participation in the documentation.

50. The ISP shall include goals and objectives that align with and support the resident's wishes and preferences regarding developing skills, working, daily routines, and engagement with their community, including community-based living options.

51. Protections, planning, services, supports, and treatments shall be coordinated through the resident's IDT and a complete and coherent ISP.

52. Protections, planning, services, supports, and treatments shall be based on reliable comprehensive assessments, conducted routinely and in response to significant changes in the resident's life.

53. GRC shall provide protections, planning, services, supports, and treatments to residents only after the resident (to the greatest extent practicable) and the resident's guardian (if there is one) have provided informed consent confirmed in writing following disclosure and understanding of all benefits and risks and appropriate strategies, if any, to mitigate the risks.

54. GRC shall ensure effective transparency, communication and information-sharing between and among professional and direct care staff regarding residents' physical and behavioral health status, and residents' integrated programs and supports, on a routine and an as-needed basis in response to potential changes in status or condition.

55. GRC shall ensure effective transparency, communication, and information-sharing between and among a resident's IDT members, the resident, and the resident's family and guardian, regarding changes in treatment or status.

56. Unless otherwise expressly indicated, the responsible IDT member(s) for each program or support included in the ISP shall review and analyze the data and other information

necessary to assess the resident's physical and behavioral health status progress and the effectiveness of current interventions. This review and analysis shall occur at least monthly, and more often if the needs of the resident dictate. If expected progress has occurred, the IDT will identify strategies to build on such success. If there is a lack of expected progress, and/or a significant change in the resident's status has occurred, then the IDT shall meet to determine if the ISP should be modified, and shall modify the ISP as appropriate.

a. These reviews shall include reviewing data for any emerging risks. When emerging risks are identified, an At-Risk Plan shall be developed and implemented consistent with the provisions of Section IV.C.iii.

57. The State shall implement and use a procedure for resolution of disagreement between IDT members. This procedure shall include mechanisms to obtain external clinical consultations when appropriate.

a. All members of the IDT shall have the ability to initiate this resolution process regarding a resident served by the IDT.

b. No IDT member shall discourage use of this resolution process.

c. No IDT member shall be retaliated against for initiating or participating in this resolution process.

C. Clinical Care

58. GRC residents shall receive quality integrated preventative, chronic, and acute clinical care and services, including psychiatric, psychological, medical, nursing, pharmaceutical, pain management, seizure management, and habilitation therapy services, consistent with current, generally accepted professional standards of care.

59. Assessments shall be performed on a regular basis and in response to developments or changes in a resident's medical, behavioral, or functional status to ensure the timely detection of and response to residents' needs.

60. Diagnoses shall be clinically appropriate and consistent with the current Diagnostic and Statistical Manual of Mental Disorders and the International Statistical Classification of Diseases and Related Health Problems.

61. Treatments, supports, and interventions shall be timely and clinically appropriate based upon assessments and diagnoses. Clinicians shall conduct direct assessments consistent with current, generally accepted professional standards of care.

62. Clinical indicators of the effectiveness of treatments, supports, and interventions shall be determined in a clinically justified manner.

63. Clinical indicators of the effectiveness of treatments, supports, and interventions shall be effectively monitored.

64. Treatments, supports, and interventions shall be modified in response to the results of monitoring of clinical indicators.

65. GRC shall routinely collect, analyze, and act on valid and reliable data sufficient to ensure that the clinical care and services provided to GRC residents are consistent with current, generally accepted professional standards and implemented in an appropriate manner. Where such data show that clinical care and services, or their implementation, do not meet such standards, GRC clinical staff shall appropriately address the deficiency.

66. GRC's quality management system shall include processes to ensure that the provision of clinical care and services at GRC are consistent with current, generally accepted professional standards and implemented in an appropriate manner. The State shall ensure data related to the provision of clinical care and services is shared with GRC's Quality Management program and that the data is valid, analyzed, and utilized for GRC's quality improvement, pursuant to the processes set forth in Section IV.K.

67. Whenever problems are identified under the processes set forth in Paragraphs 65-66, GRC shall develop and implement plans to remediate the problems.

i. Supervision & Management of Clinical Services

68. The State shall ensure appropriate and competent supervision and management of clinical services by individuals with appropriate training and credentials.

69. GRC shall employ adequate numbers of clinical staff with appropriate training, credentials, competence, and expertise to provide the clinical services identified herein to a reasonable caseload of individuals with IDD consistent with generally accepted professional standards of care.

70. Clinical staff shall demonstrate maintenance of the requisite training, credentials, competence, and expertise throughout their period of employment.

71. The State shall regularly have board-certified clinicians, who do not have a professional or personal relationship with GRC clinicians or GRC Leadership, assess the adequacy of clinical services in the clinical areas for which they are board-certified, including, at a minimum, all medical staff. The assessment findings shall be written and shared with the clinician whose work was the subject of the review and the clinician's supervisor. Action steps to remediate identified issues shall be developed as necessary. Where action steps are not deemed necessary, the rationale shall be provided in writing. The findings, action steps, and rationale for not taking action steps shall be provided to and reviewed by the Superintendent and HHS Central Office as part of a comprehensive oversight process.

72. Clinical services shall engage in and be subject to Quality Management, to include appropriate peer review and appropriate mortality reviews.

    a. For every death of a Glenwood resident, an appropriate interdisciplinary mortality review will be conducted by a Mortality Review Committee, that includes Glenwood and HHS Central Office staff with appropriate expertise, knowledge,

and skills in conducting mortality reviews, and includes at least one member not otherwise employed or compensated by the HHS.

b. No primary care provider (PCP) shall be responsible for conducting a mortality review for an individual under that PCP's care during the relevant review period.

c. The Mortality Review Committee shall continuously collect and analyze mortality data, including data from external mortality reviews, to identify trends, patterns, and problems, and shall develop and implement quality improvement initiatives to remedy such trends, patterns, and problems to the fullest extent practicable.

d. The State shall ensure that:

i. Mortality Review Committee recommendations are documented and implemented, or a reasonable and supported explanation provided;

ii. Implementation of Mortality Review Committee recommendations is effective, or, if not effective, the implementation or recommendation, as warranted, is adjusted to advance the recommendation's intended outcome.

ii. Medical Services

73. The GRC Medical Director shall be a board-certified individual with successful experience in providing medical services to individuals with IDD and in supervising medical providers. The Medical Director shall have training or experience in quality management and research, or shall undergo such training within the first six months of employment.

74. Clinical staff shall timely and appropriately respond when residents experience changes in condition, including, when appropriate, prompt coordinated transfer to a higher level of care and coordinated return from a higher level of care.

75. GRC shall effectively use specialist consultations with staff, contract staff, or external consultants. This includes ensuring:

a. There is timely referral to appropriate and competent specialists;

b. The consultant is provided with information necessary to obtaining the consultant's informed assessment and recommendations about the resident;

c. Question(s) for the specialist are identified in advance of the consultation and communicated in writing;

d. GRC shall make reasonable efforts to ensure that appropriate responses to the questions are received following the consultation;

e. The consultation report is reviewed by the resident's PCP, as well as all other IDT members whose review would be appropriate under the circumstances and provided to the resident and/or the resident's guardian; and

f. The PCP, in consultation with appropriate IDT members, documents the basis for agreeing or disagreeing with the consultant's recommendations, the actions taken in response (including obtaining a second opinion), or the basis for taking no action.

76. GRC shall ensure timely and appropriate use and review of laboratory and diagnostic testing and testing results. This includes ensuring:

a. Timely initiation of laboratory and diagnostic testing;

b. Urgent notification of critical results;

c. Review of all results by the resident's PCP, along with other IDT members as appropriate under the circumstances, and identification, development, and timely implementation of either a plan in response to abnormal results, or the basis for taking no action in response. The review, actions taken in response, or the basis for taking no action in response, shall be documented in the resident's medical file.

iii. Residents at Risk of Harm

77. The State shall implement risk management processes, including establishment of uniform risk triggers and thresholds, that enable the State to adequately address harms and risks of harm to GRC residents.

78. After a resident is identified as at risk of harm, and in response to changes in an at-risk individual's condition as measured by established at-risk criteria, the resident will receive a timely interdisciplinary assessment of services and supports. This assessment process shall begin as soon as possible after a resident is identified as at risk of harm.

79. GRC shall identify risk-relevant thresholds and shall create appropriate facility protocols to respond to the risks. Those protocols and the interdisciplinary assessment of the individual will then be used by the interdisciplinary team to establish an appropriate individualized plan of care (At-Risk Plan). Both protocols and At-Risk Plans will include preventative interventions to minimize the condition of risk. After development of the thresholds and protocols, GRC shall create and implement At-Risk Plans of care in response to risks within 14 days of identification of the risk.

80. GRC shall develop effective methods of gathering and incorporating feedback from direct care and clinical care staff so that input is received and the interdisciplinary team remains able to timely respond. Direct care staff shall provide input, receive competency-based training, and shall monitor and report on the progress of, implementation of the At-Risk Plan.

81. GRC shall revise the At-Risk Plan, its implementation, or both, as warranted based on the at-risk resident's condition. The At-Risk Plan shall be reviewed and revised as warranted as part of the annual ISP process.

iv. Nursing Services

82. Nurses shall perform comprehensive nursing assessments routinely and as necessitated by a change in resident condition; identify health care problems; communicate with PCPs regarding health care problems and changes in health status; plan, implement, and evaluate the effectiveness of nursing care; and keep appropriate records of residents' health care status and plan of care, sufficient to readily identify changes in status and residents' response to treatment.

83. Nurses shall routinely assess residents for symptoms of pain, in response to changes in client condition when one would reasonably expect pain to result, and when other relevant staff communicate the suspicion of resident pain in the event the resident is not able to verbalize pain. The nurse shall attend to and treat the residents' pain in a timely manner, communicating with the PCP or on-call provider as needed.

84. Nurses shall, in coordination with other relevant staff, conduct a routine review of each resident's health care status and the effectiveness of related interventions, and more frequent reviews when a resident's health care status so requires, and take appropriate action in response to findings of the review and assessment.

85. Nurses shall, in coordination with other relevant staff, ensure residents are appropriately protected from infection. GRC shall establish and maintain an effective infection control committee, and ensure ongoing access to and consultation with experts in infection control and infectious diseases.

86. Nurses shall, in coordination with other relevant staff, ensure residents maintain maximum skin integrity.

87. Nurses shall, in coordination with other relevant staff, ensure residents receive their medications and treatments as prescribed.

v. Psychiatric Services

88. No GRC resident shall receive psychiatric medication without having been evaluated and diagnosed, in a clinically justifiable manner, by a board eligible or board-certified psychiatrist.

89. Psychiatric medications shall not be used in the absence of a behavioral treatment program, for the convenience of staff, or as a punishment, and shall be integrated with behavioral and other interventions through combined assessment and case formulation.

90. Before the non-emergency administration of psychotropic medication, and to the extent possible before the emergency administration of a chemical restraint, the psychiatrist and PCP, and others as appropriate, shall determine whether the risks of medication outweigh the benefits of medication and whether reasonable alternative treatment strategies are likely to be less effective or more dangerous than the medication.

91. For any resident receiving psychological and psychiatric services, the resident's IDT shall determine the least intrusive and most positive interventions to treat the resident's behavioral or psychiatric condition(s), and whether the resident will best be served primarily through behavior supports, individual or group counseling, education, adaptations to the environment, adjustments to the daily routine, pharmacology, or other interventions, in combination or alone. If the IDT concludes that the resident is best served through the use of psychiatric medication, the IDT must also specify non-pharmacological treatment, interventions, or supports in order to minimize the need for psychotropic medication as much as possible.

vi. Medication

92. GRC residents shall not be prescribed a medication unless there is an appropriate diagnosis justifying prescription of the medication.

93. Upon the prescription of a new medication:

    a. Potential interactions, side effects, allergies, adverse reactions will be reviewed by nursing staff or the medical provider.

    b. There shall be a documented review by a pharmacist (on the same business day, or by the next business day for new medications prescribed on the weekend), with recommendations when clinically indicated, of:

        i. Potential interactions with the resident's current medications;

        ii. Potential consequences given the resident's diagnoses and active medical problems;

        iii. Potential side effects;

        iv. Potential allergies;

        v. Current clinically relevant laboratory and other diagnostic testing results;

        vi. The need for additional laboratory and other diagnostic testing or other measures in connection with risks associated with use of the medication;

        vii. The potential to use alternative medications to minimize the occurrence and/or severity of side effects, or interactions with the resident's current medications or active medical problems, or the severity of such interactions with underlying conditions or active medical problems; and

    c. The need to consider dose adjustments if the prescribed dosage, or the cumulative dosage of the resident's entire medication regimen, is not consistent with State policy or generally accepted standards of care. The prescriber and the resident's PCP, as well as any other clinicians as appropriate, shall document review of the pharmacist's review; agreement or disagreement with the pharmacist's

recommendations, if any; the clinically justified basis for agreeing or disagreeing; and any changes in the prescription made in light of the pharmacist's review.

94. A pharmacist shall conduct Quarterly Drug Regimen reviews to identify abnormal or sub-therapeutic values and consider, note, and make recommendations to address, as appropriate, residents' laboratory results.

95. Prescribing practitioners, the pharmacist, and other physicians as appropriate shall collaborate in monitoring the use of medications to ensure clinical justifications and attention to associated risks. Prescribing practitioners shall document consideration of the pharmacist's recommendations and, for any recommendations not followed, shall document a clinical justification for why the recommendation is not being followed.

96. GRC shall implement a review system to monitor at least monthly the prescriptions of any first-generation antipsychotic medication, two or more psychiatric or neurological medications from the same general class (e.g., two antipsychotics) to the same resident, and the prescription of three or more psychiatric or neurological medications, regardless of class, to the same resident, to ensure that the use of such medications is clinically justified and that medications that are not clinically justified are eliminated. Monitoring shall be conducted by the Pharmacy and Therapeutics Committee, which shall include: the Medical Director; the Pharmacy Director; one PCP, if available, who is not the resident's treating physician; and other appropriate staff.

    a. Before a prescriber initiates treatment with a medication that would render a person subject to the monthly review described above (e.g., by prescribing a third psychiatric or neurological medication to a resident already prescribed two such medications), the person's IDT shall meet to consider the recommended medication and alternative nonpharmacological interventions, and shall document the rationale for the selected decision.

97. GRC residents receiving psychiatric or neurologic medications shall be monitored on at least a quarterly basis, and more frequently as clinically indicated, for medication side effects using validated rating instruments such as MOSES or DISCUS. The PCP and neurologist and/or psychiatrist as appropriate shall document review of the quarterly monitoring, including a plan to respond to abnormal findings or a clinically justified basis for not acting upon abnormal findings.

98. GRC shall regularly perform drug utilization evaluations in accordance with current, generally accepted professional standards of care.

99. GRC shall identify all medications prescribed for dual purposes, and for all medications so identified, ensure ongoing collaboration between relevant disciplines (e.g. psychiatry, neurology) regarding their continued use. Collaboration among necessary disciplines regarding use of the dual-use medication shall be coordinated by the resident's PCP. To the extent a resident's existing medication is subsequently determined to be for dual purposes,

even if it was not intended to be used for dual purposes when initially prescribed, this provision shall apply to its ongoing use.

100. Within three months of the Effective Date of this agreement, GRC shall conduct an external clinical review to verify the continuing propriety of the resident's prescriptions with respect to every resident who falls into the following categories, and shall then implement the recommendations arising from that review:

a. Residents who are prescribed Dilantin (phenytoin sodium), valproic acid, Thorazine (chlorpromazine), Loxatine (loxapine), fluephenazine, perphenazine, haloperidol, primidone, or phenobarbital;

b. Residents who are prescribed oral bisphosphonates (e.g., Fosamax) and:

i. Have esophageal motility disorders;

ii. Have GERD;

iii. Are at increased risk of aspiration; or

iv. Who are unable to stand or sit upright for at least 30 minutes after dose administration.

101. GRC shall ensure the timely identification, reporting, and completion of appropriate remedial action regarding all significant or unexpected adverse drug reactions.

102. GRC shall administer medications safely. This includes:

a. Ensuring the safe dispensation and administration of medications by appropriately trained and competent staff consistent with current generally accepted professional standards of care;

b. Ensuring the supervision and training necessary to minimize medication variances;

c. Ensuring accurate, effective, and timely documentation, reporting, investigation, analyses and appropriate remedial action regarding potential and actual medication variances.

i. Potential and actual medication variances shall be reviewed by the Medication Variance Committee. The Committee shall include at least one staff member from the GRC Quality Management Department, and all Committee members shall have received training in Quality Management.

ii. The Committee shall address potential and actual medication variances using a continuous quality improvement model.

vii. Psychological Services

103. GRC shall review its psychological assessment protocols to ensure they are consistent with current, generally accepted professional standards of care, and revise them as warranted. The assessment protocols shall:

a. Include protocols for a functional behavioral assessment to identify target behaviors and the function of each target behavior;

b. Identify medical, psychiatric, environmental, diagnostic, or other reasons for target behaviors; and

c. Identify other psychological and mental health needs that may require intervention, including history of trauma.

104. In conducting the review of psychological assessment protocols set forth in Paragraph 103, GRC shall ensure that its suicide assessment protocol is consistent with current, generally accepted professional standards of care and shall revise it as needed. GRC shall ensure that staff members responsible for administering suicide assessments have training in assessing suicide risk for people with IDD and are demonstrably competent to assess such risk.

105. Within the later of 12 months from the Effective Date or one month from the resident's admission, and thereafter as often as needed, the State shall ensure that a GRC Behavioral Health Professional completes a psychological assessment of each GRC resident, which shall include a functional behavioral assessment for at least those residents with behavioral needs, pursuant to GRC's psychological assessment protocols set forth in Paragraph 103. Those residents needing psychological services other than BSPs shall receive such services in a documented manner enabling progress to be measured in a reliable manner to determine the effectiveness of treatment. Absent extraordinary circumstances (i.e. shortage of available providers for a service that is not typically needed by the Target Population), those residents shall begin receiving such services within four weeks of the psychological assessment. Documentation shall reflect efforts to initiate recommended services and that barriers to initiating services are addressed.

106. Psychological assessments shall be based on current, accurate, and complete clinical and behavioral data.

107. By one month from the date of the resident's assessment, GRC shall develop an individual BSP, consistent with the resident's ISP and with current, generally accepted professional standards and taking into account relevant factors such as history of trauma and other mental health needs, for each resident who is exhibiting behaviors that constitute a risk to the health or safety of the resident or others, or that serve as a barrier to learning and independence, and that have been resistant to less formal interventions. By 14 days from obtaining necessary approvals and consents, GRC shall implement the BSP.

108. Each resident with behavioral health needs as determined by the assessment process set forth in Paragraphs 103-106 shall be assigned a Behavioral Health Professional whose caseload and expertise are sufficient to meet the resident's behavioral health needs. Any resident with severe behavioral needs (including any resident who engages in intense or frequent self-injury, aggression, pica, or property destruction) shall be assigned a Behavioral Health Professional who is a Board Certified Behavioral Analyst.

109. Each Behavioral Health Professional shall be responsible for a caseload of residents with needs within the Behavioral Health Professional's scope of practice and experience. The size of each caseload and the level and type of Behavioral Health Professional expertise shall be commensurate with the severity of needs of residents on that caseload.

110. GRC shall retain a sufficient number of Behavioral Health Professionals who are Board Certified Behavioral Analysts to meet the behavioral health needs of GRC's residents. The State may utilize recruitment incentives, including on-the-job training to obtain BCBA certification, with appropriate supervision, consistent with generally accepted professional standards.

111. GRC shall provide residents requiring a BSP with individualized services and comprehensive programs developed by a Behavioral Health Professional that are trauma-informed; consider the mental health needs of the residents; promote the growth, development, and independence of all residents; minimize regression and loss of skills; and ensure reasonable safety, security, and freedom from undue use of restraint.

112. GRC shall employ a qualified Director of Psychology who is responsible for maintaining a consistent level of psychological care throughout the GRC. The Director of Psychology shall be a Board Certified Behavioral Analyst with a minimum of five years of experience working with adults with IDD with serious behavioral needs and co-occurring mental health diagnoses, and with demonstrated success managing staff in the provision of behavioral health services.

113. GRC shall conduct reliable reviews to assess the quality of behavioral assessments and BSPs of each Behavioral Health Professional at least semi-annually. The reviews shall be conducted by Behavioral Health Professionals who did not prepare the behavioral assessments and BSPs under review. Each resident's behavioral assessment and BSP shall be reviewed at least every two years, and each resident with severe behavioral needs (including any resident who engages in intense or frequent self-injury, aggression, pica, or property destruction) shall have their behavioral assessment and BSP reviewed through this process at least every six months. The findings of the peer-based reviews shall be utilized to improve behavioral assessments, BSPs, and behavioral programming.

114. GRC shall develop and implement standard procedures for collection of valid and reliable data, including methods to collect data regarding instances of behavior as it occurs and to monitor and review each resident's progress in meeting the goals of the resident's BSP, consistent with generally accepted standards of care. At least monthly, Behavioral Health Professionals shall review data collected pursuant to these procedures to assess progress,

and shall re-evaluate and promptly revise assessments and interventions if target behaviors do not improve or have substantially changed.

115. Documentation regarding the BSP's implementation shall be gathered and maintained in such a way that progress can be measured to determine the frequency and variability of behavioral incidents and the effectiveness of treatment. Documentation shall be maintained to permit clinical review of medical conditions, psychiatric treatment, and use and impact of psychotropic medications.

116. BSPs at GRC shall be written so that they can be understood and implemented by direct care staff.

117. BSPs at GRC shall be implemented by all staff as written, and significant deviations from residents' BSPs shall be reported to the resident's Behavioral Health Professional and GRC administration, and appropriate action shall be taken.

118. All Behavioral Health Professionals and psychology assistants shall successfully complete annual competency-based training in providing trauma-informed behavioral services to individuals who have IDD and challenging behaviors.

119. All staff responsible for training and monitoring implementation of behavioral programming shall be demonstrably competent to implement behavioral programming and shall be monitored by Behavioral Health Professionals.

120. All direct contact staff and their supervisors shall successfully complete competency-based training on severe behavioral needs, the co-occurrence of mental health needs and IDD, and the principles of applied behavioral analysis at least annually. GRC direct contact staff and their supervisors shall successfully complete competency-based training on the overall purpose and objectives of the specific BSPs for which they are responsible and the implementation of those plans, annually and every time a new BSP is written, a BSP is changed, or the staff member becomes responsible for the support of a new individual.

121. GRC shall regularly monitor the implementation of BSPs, including assessing staff's knowledge through assessments and observations that determine the staff person's knowledge and skills about the BSP in a context similar to one in which such knowledge or skills would be required.

122. Behavioral Health Professionals shall assess the mental health needs of GRC residents pursuant to the protocols in Paragraphs 103-106 at least annually, but as often as needed. GRC shall ensure that needed counseling and other therapeutic interventions are available and provided to residents.

D. Restrictive Interventions

123. GRC shall provide residents with a safe and humane environment and ensure they are protected from harm, including the unnecessary use of restrictive interventions, consistent with current, generally accepted professional standards of care.

124. All residents' restrictive interventions and alternative positive interventions shall be discussed at the monthly integrated reviews, to ensure that a plan to implement the alternative interventions is being implemented, and to update or revise the plan to implement the alternative interventions as warranted.

125. GRC's Psychology Department shall routinely collect, analyze, and act on valid and reliable data sufficient to ensure that the use of restrictive procedures at GRC is consistent with current, generally accepted professional standards and implemented in an appropriate manner.

126. GRC's quality management system shall include processes to ensure that the use of restrictive procedures at GRC is consistent with current, generally accepted professional standards and implemented in an appropriate manner. The State shall ensure that the Psychology Department shares restrictive intervention data with GRC's Quality Management program and that the data is valid, analyzed, and utilized for GRC's quality improvement, pursuant to the processes set forth in Section IV.K.

127. Whenever problems are identified under the processes set forth in Paragraphs 125-126, GRC shall develop and implement plans to remediate the problems.

i. Restraints

128. Within six months of the Effective Date, the State shall review GRC's restraint policies and practices and conform them to the requirements of this Section. The policies shall identify restraints that may be used and the criteria for their use, and shall categorize permitted restraints by level of restriction.

129. Restraints shall only be used:

a. when the resident poses an immediate and serious risk of harm to him- or herself or others and if the restraint is the least restrictive intervention necessary;

b. as a last resort and after a graduated range of less restrictive measures has been exhausted or considered in a clinically justifiable manner;

c. in the least restrictive form and duration of restraint necessary and appropriate for the circumstances; and

d. in accordance with applicable written policies, procedures, and plans governing restraint use.

130. Restraints shall not be used for punishment, for convenience of staff, or in the absence of, or as an alternative to, treatment.

131. Under no circumstances shall prone restraints be used.

132. Restraints shall be terminated as soon as the resident is no longer a danger to him/herself or others.

133. No restraint shall be used that is prohibited by the individual's medical orders or ISP. If medical restraints are required for routine medical or dental care for an individual, the ISP for that individual shall include treatments or strategies to minimize or eliminate the need for restraint.

134. Within 30 minutes after a resident is placed in restraint, a physician, physician's assistant, nurse practitioner, or a Registered Nurse with training in application and assessment of restraint, shall conduct and document a face-to-face examination of the resident, including a check for restraint-related injury.

135. Staff who are competent to apply and assess the use of the restraint, as demonstrated by successful annual certification in the restraint's use, and who are not involved in administering the restraint, shall check the resident as soon as possible but, in the exceptional circumstances where restraints exceed 15 minutes, no later than 15 minutes from the start of the restraint, to review the application and consequence of restraint.

136. A registered nurse shall monitor and document vital signs and mental status of a resident in restraints at least every 30 minutes from the start of the restraint, and at the restraint's conclusion, except for medical restraint pursuant to a physician's order. In each instance of a medical restraint, the physician shall specify the schedule and type of monitoring required.

137. Every resident in physical or medical mechanical restraint shall receive opportunities to exercise restrained limbs, to eat as near meal times as possible, to drink fluids, and to use a toilet or bed pan, consistent with generally accepted professional standards of care; and shall be under continuous one-to-one supervision.

138. Mechanical restraints shall not be used other than as prescribed for necessary medical care.

139. Every use of restraint shall be documented consistent with generally accepted professional standards of care.

140. After three instances of restraint of a resident in 30 days or an increasing trend in restraint data over the course of three months of a resident, the IDT shall examine and refine that resident's behavioral programming using data-based decision-making. In conducting this review, the IDT shall:

a. review the individual's adaptive skills and biological, medical, psychosocial factors;

b. review possibly contributing environmental conditions;

c. review or perform assessments of the behavior provoking restraints;

d. develop (if one does not exist) or revise (if necessary) and implement a BSP based on that individual's particular strengths, specifying the objectively defined behavior to be treated that leads to the use of the restraint; alternative functionally equivalent, positive adaptive behaviors to be taught to the individual to replace the behavior that initiates the use of the restraint; and other programs, where possible, to reduce or eliminate the use of such restraint. The type of restraint authorized, the restraint's maximum duration, the designated approved restraint situation, and the criteria for terminating the use of the restraint shall be set out in a separate safety plan, the necessity for which shall be reassessed at least every 30 days;

e. ensure that the individual's treatment plan is implemented with a high level of treatment integrity, i.e., that the relevant treatments and supports are provided consistently across settings and fully as written upon each occurrence of a targeted behavior; and

f. as necessary, assess and revise the BSP.

141. Within three months of execution of the agreement, before working with residents, all GRC staff responsible for applying restraints shall have successfully completed competency-based training on applicable BSPs and safety plans; approved verbal intervention and redirection techniques; approved restraint techniques; and adequate supervision of any resident in restraint.

142. GRC Behavioral Health Professionals shall be involved in the selection of any crisis management system used by GRC. All Behavioral Health Professionals at GRC shall have a high degree of expertise with the crisis management system. Training shall be conducted by certified trainers.

143. Within six months after the Effective Date, for each GRC resident restrained from January 1, 2020 until the Effective Date, the resident's IDT shall review the resident's BSP and ensure that it contains the objectively defined behavior to be treated that leads to use of the restraint and alternative, positive adaptive behaviors to be taught to the resident to replace the behavior that initiates the use of restraint, as well as other programs, where possible, to reduce or eliminate the use of such restraint.

ii. Seclusion

144. By six months from the Effective Date, GRC shall eliminate, to the extent practicable, the use of seclusion.

145. GRC shall ensure that to the extent seclusion is used, it is used only if the resident poses an immediate and serious risk of harm to him/herself or others; only as a last resort and after a graduated range of less restrictive measures has been exhausted or considered in a clinically justifiable manner; only for reasons other than as punishment, for convenience of staff, or in the absence of or as an alternative to treatment; and only in accordance with applicable written policies, procedures, and plans governing seclusion.

146. Seclusion shall not be implemented without a recommendation by the resident's assigned Behavioral Health Professional and inclusion in the resident's BSP, following a thorough assessment reliably identifying the causes and functions of, and precursors to, the behaviors leading to seclusion and a documented exhaustion of less restrictive interventions. Seclusion shall not be implemented for any resident without approval by the Human Rights Committee.

147. Seclusion shall not be implemented unless the resident has a BSP, developed by the resident's Behavioral Health Professional and implemented by the resident's IDT, identifying the specific criteria for use and discontinuation of seclusion. Such a plan shall set forth specific steps to be taken by the resident's IDT and Behavioral Health Professional to address the behaviors that led to the resident's seclusion and to minimize and ultimately eliminate its use. Use of seclusion, and the corresponding behavioral interventions, shall be subject to the processes described in Paragraph 140.

148. Seclusion shall not be implemented until the resident's IDT, GRC's Human Rights Committee, and guardian have approved the use of the seclusion following a thorough discussion of seclusion's likely consequences. Within seven days of the initiation of use of seclusion for a GRC resident, HHS Central Office shall review the use of seclusion and ensure that sufficient protections are in place. Seclusion shall not be approved in a resident's BSP for a period of more than 30 days at a time without reapproval by the resident's Behavioral Health Professional, the Director of Psychology, the resident's IDT, GRC's Human Rights Committee, the resident's guardian, and HHS Central Office.

149. No resident experiencing seclusion shall be denied access to typical items that a resident at GRC has access to, absent a well-defined treatment reason and approval from the resident's Behavioral Health Professional, guardian, and IDT; the Director of Psychology; and GRC's Human Rights Committee. If a resident is denied access to such items, GRC shall ensure that the resident's BSP provides a plan to return access and that such a plan is implemented.

iii. Other Restrictive Interventions

150. GRC shall ensure that other restrictive interventions, such as heightened levels of supervision, are used only as needed, in conjunction with positive behavioral interventions that address functionally equivalent replacement behaviors, and after a range of less restrictive measures have been exhausted. GRC shall ensure that any restrictive interventions are used only consistent with current, generally accepted professional standards of care.

151. In the event of an imminent safety risk, brief restrictive interventions may be used for up to 15 minutes, and may continue for up to 12 hours with the advance approval of the Administrator on Duty.

152. Unless there is an imminent safety risk, no restrictive intervention shall be implemented until:

a. The resident's IDT, GRC's Human Rights Committee, the Director of Psychology, and the resident's guardian have approved the use of the restrictive intervention following a thorough discussion of likely consequences; and

b. When the Director of Psychology is absent, an appropriate acting Director of Psychology may review and determine whether to approve on the Director's behalf. The Director of Psychology shall subsequently review and determine whether to approve within 5 business days of their return.

c. The resident has a BSP, developed by the resident's Behavioral Health Professional and implemented by the resident's IDT, identifying the specific criteria for use and discontinuation of the restrictive intervention. The BSP shall be developed from a thorough functional behavioral assessment that reliably identifies the causes and functions of, and precursors to, the behaviors leading to restrictive interventions and a documented exhaustion of less restriction alternatives. The BSP shall set forth specific steps to be taken by the resident's IDT and Behavioral Health Professional to address the behaviors that led to the resident's restrictive interventions and to minimize and ultimately eliminate the intervention's use. Use of restrictive interventions, and the BSP to address the behaviors leading to restrictive interventions, shall be subject to the processes described in Paragraph 140.

153. After three instances of a restrictive intervention of a resident in 30 days or an increasing trend in restrictive intervention data over the course of three months of a resident, the IDT shall examine and refine the resident's behavioral programming as set forth in Paragraph 140.

154. Restrictive interventions shall not be approved in a resident's BSP for a period of more than 90 days at a time without reapproval by the resident's Behavioral Health Professional, the Director of Psychology, the resident's IDT, GRC's Human Rights Committee, and the resident's guardian.

E. Engagement and Skill Acquisition Programs

155. GRC shall provide habilitation, vocational training, education, and skill acquisition programs consistent with current, generally accepted professional standards of care.

156. GRC shall provide residents with adequate habilitation services, including individualized training, education, and vocational and skill acquisition programs developed and implemented by IDTs to promote the growth, development, integration, and independence of all residents, to minimize regression and loss of skills, and to ensure reasonable safety, security, and freedom from undue use of restraint.

157. Residents at GRC shall be provided meaningful and appropriate vocational, day, and skill-acquisition programming, including programming outside their homes, on a daily basis, unless the resident refuses to participate, has restrictions on such programming in his or her ISP or BSP, or it is contraindicated by community health restrictions. Residents shall

also be provided integrated community-based activities unless the resident refuses to participate or has restrictions on such programming in his or her ISP or BSP. If the resident has restrictions on such programming or community-based activities resulting from the resident's behavior, the resident's Behavioral Health Professional shall develop a plan to minimize the existence of those behavioral barriers and the resulting restrictions.

158. GRC shall conduct annual assessments, with quarterly reviews, of residents' preferences, strengths, skills, needs, and barriers to community integration, in the areas of living, working, and engaging in leisure activities. For residents with behavioral barriers to community integration, the resident's Behavioral Health Professional shall assist with developing a Community Integration Plan to minimize the existence of behavioral barriers.

159. GRC shall use the information gained from the assessment and review process to develop, integrate, and revise programs of training, education, and skill acquisition to address each resident's needs. Such programs shall:

a. Be current, individualized, and integrated with other supports and services;

b. Incorporate the person's preferences and strengths;

c. Specify individualized, observable and/or measurable goals/objectives, the strategies to be employed, and the necessary supports to attain identified outcomes, in sufficient detail to enable staff to appropriately implement the programs;

d. Include interventions, strategies and supports that: (1) effectively address the resident's needs for services and supports; and (2) are practical and functional in the most integrated setting consistent with the resident's needs;

e. Include to the degree practicable training opportunities in community settings; and

f. Identify the data to be collected and/or documentation to be maintained, and the frequency of data collection, in order to permit the objective analysis of the resident's progress, the person(s) responsible for the data collection, and the person(s) responsible for the data review.

160. The State shall ensure that all GRC direct care staff have successfully completed competency-based training on the implementation of the habilitation programs, including training, education, and skill acquisition programs, of the residents they work with, annually and every time a new habilitation program is implemented, a habilitation program is changed, or the staff member becomes responsible for the support of a new individual. This training shall include the purpose and objective of the particular habilitation program so that the staff implementing the program understand what the program is intended to achieve. Up to one-quarter of the staff assigned to work with a particular resident at any point in time may receive abbreviated training or information in lieu of competency-based training if

necessary to meet basic staffing requirements, as approved by the Superintendent, because they are pulled staff.

161. GRC shall routinely collect, analyze, and act on valid and reliable data sufficient to ensure that the habilitation, training, education, and skill acquisition programs provided to GRC residents are consistent with current, generally accepted professional standards and implemented in an appropriate manner.

162. GRC's quality management system shall include processes to ensure that the habilitation, training, education, and skill acquisition programs provided to GRC residents are consistent with current, generally accepted professional standards and implemented in an appropriate manner. The State shall ensure that data related to such programs is shared with GRC's Quality Management program and that the data is valid, analyzed, and utilized for GRC's quality improvement, pursuant to the processes set forth in Section IV.K.

163. Whenever problems are identified under the processes set forth in Paragraphs 161-162, GRC shall develop and implement plans to remediate the problems.

F. Recordkeeping

164. GRC shall maintain complete and accurate records.

165. GRC shall ensure pertinent information about assessment, treatment, and diagnosis, including information justifying decisions not to treat or diagnose, is accurately and timely documented within the resident's integrated electronic health record.

166. GRC shall maintain and produce records in a manner that clearly demonstrates:

a. The time and date when a particular record or entry was created or entered;

b. The identity and job title of the person creating or entering the record or entry;

c. The time and date to which the record or entry pertains;

d. Whether the record or entry was created or entered timely according to State policy; and

e. If a record or entry is subsequently changed:

i. The time and date the change is made;

ii. The identity and job title of the person making the change;

iii. The reason for the change;

iv. The nature of the change; and

v. A version of the record or entry as it existed before it was changed.

G. Incident Management

167. GRC shall implement and maintain policies, procedures and practices that include a commitment that GRC shall not tolerate abuse or neglect of individuals and that staff are required to report abuse or neglect of individuals.

168. GRC shall review, revise, as appropriate, and implement incident management policies, procedures and practices. Such policies, procedures and practices shall require:

a. Staff to immediately report serious incidents, including death, abuse, neglect, exploitation, and serious injury, as follows:

i. for deaths, abuse, neglect, and exploitation, report should be made to the Superintendent (or that official's designee) and such other officials and agencies as warranted, consistent with Iowa law; and

ii. for serious injuries and other serious incidents, report should be made to the Superintendent (or that official's designee). Staff shall report these and all other unusual incidents, using standardized reporting.

b. Mechanisms to ensure that, when serious incidents such as allegations of abuse, neglect, exploitation or serious injury occur, Center staff take immediate and appropriate action to protect the residents involved, including removing alleged perpetrators, if any, from direct contact with residents pending either the investigation's outcome, or where warranted based on a preliminary assessment as set out at Paragraphs 171-174.

c. Competency-based training, at least yearly, for all staff on recognizing and reporting potential signs and symptoms of abuse, neglect, and exploitation, and maintaining documentation indicating completion of such training.

d. Notification of all staff when commencing employment and at least yearly thereafter of their obligation to report abuse, neglect, or exploitation. All staff persons who are mandatory reporters of abuse or neglect shall sign a statement that shall be kept at Glenwood evidencing their recognition of their reporting obligations. Glenwood shall take appropriate personnel action in response to any mandatory reporter's failure to report abuse or neglect.

e. Mechanisms to educate and support residents and primary correspondents (i.e., a guardian or another person, identified by the IDT, who has significant and ongoing involvement with a resident who lacks the ability to provide legally adequate consent and who does not have a guardian) to identify and report unusual incidents, including allegations of abuse, neglect and exploitation.

f. Posting in each living unit and day program site a brief and easily understood statement of residents' rights, including information about how to exercise such rights and how to report violations of such rights.

g. Mechanisms for residents, visitors, and other persons to report anonymously allegations of abuse, neglect, exploitation, other possible violations of residents' rights, or other unusual incidents.

h. Procedures for referring, as appropriate, allegations of abuse and/or neglect to law enforcement.

i. Mechanisms to ensure that any staff person, resident, family member or visitor who in good faith reports an allegation of abuse or neglect is not subject to retaliatory action, including reprimands, discipline, harassment, threats or censure. A staff person who reports an incident but does not do so in an appropriate or timely manner may be subject to appropriate counseling or discipline.

j. Audits, at least semi-annually, to determine whether significant resident injuries are reported for investigation.

169. The State shall develop and implement policies and procedures to ensure timely and thorough investigations of all abuse, neglect, exploitation, death, theft, serious injury, and other serious incidents involving residents. Such policies and procedures shall:

a. Provide for the conduct of all such investigations by qualified investigators who have training in working with people with IDD, and who are not within the direct line of supervision of the alleged perpetrator, with assistance, where appropriate, from an appropriate clinician who is not within the direct line of supervision of the alleged perpetrator.

b. Require the cooperation of Glenwood staff with outside entities that are conducting investigations of abuse, neglect, and exploitation within the bounds of their existing legal authority.

c. Ensure that investigations are coordinated with any investigations completed by law enforcement agencies so as not to interfere with such investigations.

d. Provide for the safeguarding of evidence.

e. Require that an investigation of each serious incident commence within 24 hours or sooner, if necessary, of the incident being reported.

f. Require that an investigation of each serious incident be completed within 10 calendar days of the incident being reported unless, where extraordinary circumstances exist (i.e. critical evidence is temporarily unavailable due to reasons beyond the investigator's control), the Superintendent or Chief of the Department of Inspections & Appeals Bureau of Special Services and Adult Services, as applicable, grants a written extension. The need for an extension of time frame for investigation shall be reported to HHS Central Office. HHS Central Office shall track and trend the number of extensions requested and take appropriate remedial action.

g. Require that an investigation of each serious incident result in written report, including a summary of the investigation, findings and, as appropriate, recommendations for corrective action. The report shall be sufficient to provide a clear basis for its conclusion. The report shall set forth explicitly and separately, in a standardized format:

i. each serious incident or allegation of wrongdoing;

ii. the name(s) of all witnesses;

iii. the name(s) of all alleged victims and perpetrators;

iv. the names of all persons interviewed during the investigation;

v. for each person interviewed, an accurate summary of topics discussed, a recording of the witness interview or a summary of questions posed, and a summary of material statements made;

vi. all documents reviewed during the investigation; all sources of evidence considered, including previous investigations of serious incidents involving the alleged victim(s) and perpetrator(s) known to the investigating agency;

vii. the investigator's findings; and

viii. the investigator's reasons for his/her conclusions.

h. Require that the written report, together with any other relevant documentation, shall be reviewed by staff supervising investigations to ensure that the investigation is thorough and complete and that the report is accurate, complete and coherent. Any deficiencies or areas of further inquiry in the investigation and/or report shall be addressed promptly.

i. Require that Glenwood shall also prepare a written report, subject to the provisions of subparagraph h, for each unusual incident that does not meet the criteria for serious incident.

j. Require that whenever disciplinary or programmatic action is necessary to correct the situation and/or prevent recurrence, Glenwood shall implement such action promptly and thoroughly, and track and document such actions and the corresponding outcomes.

k. Require that records of the results of every investigation shall be maintained in a manner that permits investigators and other appropriate personnel to easily access every investigation involving a particular staff member or individual.

170. For all sentinel events (unexpected events involving death or serious injury), Glenwood shall conduct an effective root cause analysis of the incident. Glenwood shall ensure the implementation of all recommendations identified by such an analysis or, in the alternative,

document a substantiated and compelling justification for not implementing a recommendation. Glenwood shall track the effectiveness of such recommendations and, if such recommendations do not have their anticipated or intended effect, shall make adjustments to such recommendations or their implementation.

171. Glenwood may conduct a preliminary assessment of an allegation of abuse, neglect, or exploitation, solely for purposes of determining staff assignments, where:

a. Within the previous six months, the resident has made four or more allegations of abuse, neglect, or exploitation, all of which were determined to be unfounded (i.e. lacking any evidence that the action alleged to be abuse, neglect, or exploitation occurred);

b. The allegation fits the characteristics of the resident's previous allegations that were determined to be unfounded, and was made within 30 days of such a previous allegation;

c. An initial assessment shows no evidence other than the resident's allegation that the alleged conduct occurred; and

d. The resident has a BSP or other support plan that includes:

i. Identification of what may be maintaining the behavior of making unfounded allegations,

ii. Methodology for accurately counting the frequency of unfounded allegations,

iii. Establishment of relevant individualized prevention protocols to reduce future likelihood of the behavior occurring (e.g., teaching of alternative behaviors, increasing the number and types of activities, providing access to preferred staff),

iv. Regular review of the effectiveness of the protocols,

v. Modifications to the protocols if determined to not be effective,

vi. Explicit language that allegations are not prohibited or restricted, and

vii. A requirement that the resident receive documented training in rights and responsibilities.

172. Where a preliminary assessment is permitted, Glenwood's Superintendent or designee must immediately remove the alleged perpetrator(s) from contact with residents:

a. until the full investigation is completed; or

b. until, after reviewing the preliminary assessment and any other relevant information, Central Office determines that the risk to residents from contact with the alleged perpetrator(s) on the Center's grounds has been sufficiently

minimized, at which time the Superintendent may allow the alleged perpetrator(s) to have continued on-campus client contact, but only with ongoing supervision (i.e. frequent, intermittent visual observation over the course of a person's shift) of the alleged perpetrator(s) by a supervisor.

173. Pending the full investigation's completion, the alleged perpetrator(s) shall not have off-grounds contact with residents.

174. The preliminary assessment shall:

a. Not conflict or interfere with the concurrent full investigation conducted by Glenwood or State investigators;

b. Focus exclusively on determining the appropriate action to take regarding the work duty assignment of the alleged perpetrator(s);

c. Where the preliminary assessment recommends allowing the alleged perpetrator to work in a resident contact position, provide the rationale for doing so; and

d. Require the prior review and approval of the Superintendent or the Administrator On Duty.

175. Glenwood shall track unusual incidents and investigation results and analyze trends. Trends shall be tracked and analyzed by the categories of the type of incident; staff alleged to have caused the incident; individuals directly involved; location of incident; date and time of incident; cause(s) of incident; and outcome of investigation.

176. Before permitting a staff person (whether full-time or part-time, temporary or permanent) or a person who volunteers on more than five occasions within one calendar year to work directly with any resident, the State shall investigate, or require the investigation of, the staff person's or volunteer's criminal history and factors such as a history of perpetrated abuse, neglect or exploitation, in order to determine whether there is an indication that the staff person or volunteer would pose a risk of harm to residents. Volunteers for whom an investigation has not been completed shall be directly supervised by a State staff person when the volunteer is working directly with residents.

H. Individual Support Planning, Discharge Planning, and Transition from Resource Center

177. To ensure that individuals are served in the most integrated setting appropriate to their needs, the State shall develop and implement individual support planning, discharge planning, and transition processes at Glenwood, consistent with the terms of this Agreement and person-centered principles, within six months of the Effective Date.

178. All residents shall participate in their individual support planning, discharge planning, and transition planning to the maximum extent practicable, unless the individual chooses not to participate. All residents shall be provided the necessary support (including, but not

limited to, communication supports) to ensure that they have a meaningful role in the process.

i. Individual Support and Discharge Planning

179. An individual support plan (ISP) and discharge plan shall be prepared consistent with the terms of this Agreement for all residents within 30 days of admission or readmission to Glenwood, and shall be updated at least annually thereafter and more frequently as appropriate.

180. Discharge planning shall begin upon admission and shall continue throughout an individual's stay at Glenwood. It shall be based on the presumption that, with sufficient supports and services, all residents (including residents with complex behavioral and/or medical needs) can live in an integrated setting.

181. Individual support and discharge planning shall assist all residents in achieving outcomes that promote their growth, well-being, and independence, based on their individual strengths, needs, goals, and preferences, in the most integrated settings in all domains of their lives (such as community living, activities, employment, education, recreation, healthcare, and relationships).

182. The ISP and discharge plan shall integrate information from the behavior support plan; crisis plan; physical and nutritional management plan; clinical, medical, and nursing plans; skill acquisition programs; and other evaluations and assessments.

183. Each resident's ISP shall:

a. Be prepared by the IDT as defined above;

b. Be consistent with current, generally accepted professional standards of care and person-centered planning principles;

c. Be based on reliable comprehensive assessments, conducted routinely and in response to significant changes in the individual's life as specified in appropriate GRC protocols;

d. Identify individualized protections, services, supports, and treatments;

e. Identify the individual's strengths, preferences, needs, and desired outcomes;

f. Specify individualized, observable and/or measurable goals/objectives that align with and support the individual's wishes and preferences regarding developing skills, working, daily routines, and engagement with their community (including exploring community-based living options) and specify the services and supports and strategies needed to achieve each goal and objective, build on the individual's strengths and preferences, and overcome identified barriers to living in the most integrated setting appropriate;

g. Identify the amount, duration, and scope of all necessary services and supports, the methods for implementation, time frames for completion, and the staff responsible.

184. The IDT shall prepare a discharge plan for each resident. Each resident's discharge plan shall:

a. Be derived from the ISP and developed in accordance with the requirements for individual support planning set forth in Paragraph 183;

b. Identify the barriers preventing the individual from transitioning to the most integrated setting appropriate and a plan for addressing those barriers. For individuals with a history of readmission or crises, the factors that led to readmission or crises shall be identified and addressed;

c. Describe at a general level how each of the services and supports the individual currently receives could be provided in the community;

d. Describe any other supports and services that would allow the individual to transition successfully to a home in the community and avoid unnecessary readmission to an institutionalized setting, regardless of whether those services and supports are currently available;

e. Document the information provided to the individual and, where applicable, the Authorized Representative, regarding community options, including the date and method of communication, in accordance with Section H.i-ii;

185. If the IDT determines that necessary supports and services are unavailable in the community, it shall document the services and supports it believes are necessary for the individual; the basis for those determinations; and the efforts made to identify those services and supports (and/or reasonable alternatives) in the community.

186. In developing discharge plans, staff who are part of the IDT shall provide to individuals and, where applicable, their Authorized Representatives, specific options for community placements, services, and supports identified through the steps described above, and the opportunity to discuss and meaningfully consider those options.

187. Staff who are part of the IDT shall coordinate with community providers that offer the placements, services, and supports identified in the discharge plan, and give individuals and, where applicable, their Authorized Representative, opportunities to speak with those providers, visit community placements (including, where feasible, overnight visits) and programs, and facilitate conversations and meetings with individuals currently living in the community and their families, regardless of whether the resident or, where applicable, their Authorized Representative, has made a choice regarding options;

188. Notwithstanding the State's rights under 42 C.F.R. § 483.440(b)(4), in the event that a resident or, where applicable, Authorized Representative opposes the IDT's proposed

options for placement in a more integrated setting after being provided the information and opportunities described in Section H.i-ii, the IDT shall:

a. Identify, and make reasonable efforts to resolve, the concerns of individuals and/or their Authorized Representatives prior to making a determination with regard to community placement;

b. Develop and implement individualized strategies to address concerns and objections to community placement; and

c. Document the steps taken to resolve the concerns of individuals and/or their Authorized Representatives and provide information about community placement.

ii. In-reach and Community Engagement

189. Upon admission, the State shall provide all residents and where applicable their Authorized Representatives, regular individualized, reliable information regarding community options in a way that enables them to make an informed decision about community transition. This shall include: holding individualized discussions, at least every six months, about a range of community options and alternatives, presented in a way the person can understand; addressing concerns about community living; and providing information about the benefits of community living options. In addition, the State shall provide all residents, and where applicable their Authorized Representatives, frequent (at least quarterly) individualized opportunities to visit community-based residential and vocational settings and to meet with other individuals with IDD who are living, working, and receiving services in integrated settings, with those individuals' families, and with community providers.

190. All staff responsible for directing, managing, or coordinating discharge planning and other informational activities regarding community options (including the Qualified Intellectual Disability Professional (QIDP); the Community Integration Manager (CIM); and social work, case management, and Money Follows the Person (MFP) staff) shall have sufficient knowledge about community services and supports to: propose appropriate options about how an individual's needs could be met in a more integrated setting; present individuals and, where applicable, their Authorized Representatives with specific options for community placements, services, and supports; and, together with providers, answer individuals' and Authorized Representatives' questions about community living.

191. In collaboration with the MCOs and community providers, the State shall develop and provide competency-based training and information for Glenwood and MCO staff about the provisions of this Agreement, staff obligations under the Agreement, current community living options, the principles of person-centered planning, and effective community options counseling. These trainings will be provided to applicable disciplines during initial orientation and annually thereafter.

192. All residents shall be provided opportunities for engaging in community activities to the fullest extent feasible, consistent with their identified needs and preferences.

iii. Transition Planning

193. All residents shall be offered a meaningful choice of community providers consistent with their identified needs and preferences. In looking for places for the individual to live, the IDT shall evaluate the type of setting most likely to ensure a successful transition (e.g. number of roommates; urban or rural; preferred geographic location; proximity to family), based on the individual's strengths, preferences, and needs.

194. IDTs shall assist the resident and, where applicable, their Authorized Representative in choosing a provider, after providing the opportunities described in Section H.i-ii, and ensure that providers are identified and engaged in preparing for the resident's transition.

195. Once a specific provider is selected by an individual, the State shall require (absent extraordinary circumstances) the provider to actively participate in the transition of the individual from Glenwood to the future setting. This shall include, as warranted by the individual's needs and preferences, repeated opportunities for the individual to visit the provider's home for meals, overnight stays, and other experiences enabling the individual to become familiar and comfortable with the home.

196. All residents who transition from Glenwood to a more integrated setting shall have the right to a return agreement, which will guarantee a right to return to either State Resource Center, as long as the request is made within six months after the date of transition.

a. Upon receiving a request to return, the State shall ensure:

i. The identification of barriers with regard to community placement;

ii. Implementation of individualized strategies to resolve those barriers (including, as appropriate, strategies to support the community service provider's ability to care for and support the individual, and to thoroughly search for other community service options); and

iii. Documentation of the steps taken to resolve the barriers with regard to community placement.

b. If after two months from the receipt of a request to return, the individual or, where applicable, their Authorized Representative determines that the issues cannot be resolved, the individual will be permitted to return to either State Resource Center.

197. Once a resident has selected a provider, and the provider agrees to serve the individual, transition shall occur within a planned and appropriate time frame (no longer than six weeks, absent conditions beyond the State's control). If transition does not occur within the planned timeframe, the reasons it did not occur shall be documented and a new time frame for discharge will be developed by the IDT. Where transition does not occur within three months of selecting a provider, the IDT shall identify the barriers to discharge and notify the Superintendent and Community Integration Manager in accordance with Section H.iv below.

198. Each individual transitioning from Glenwood shall have a current transition plan, updated within 30 days prior to the individual's discharge.

199. Based on the resident's ISP and discharge plan, the IDT shall identify in the transition plan the individual's preferences and desired outcomes, and all needed supports, protections, and services (including amount, duration, and scope) to ensure successful transition to the new living environment. The transition plan shall identify:

a. Assistance to be provided by Glenwood to the receiving setting;

b. Coordination with and training of the receiving setting's staff; and

c. Who, by name, will take what specific actions, and when, to deliver all needed supports, protections, and services for the individual, or ensure that they are in place.

200. The State, in consultation with the IDT, shall determine the essential supports needed for successful and optimal transition.

a. The State shall ensure that essential supports are in place prior to the individual's discharge from Glenwood, including behavioral supports, a crisis plan, and provision for both physical and mental health care. This determination will be documented.

b. The absence of those services and supports identified as non-essential by the State, in consultation with the IDT, shall not be a barrier to transition. However, supports and services identified as non-essential shall be in place 60 days from the individual's discharge.

iv. Community Integration Management

201. The State will create a full time Community Integration Manager ("CIM") position. The CIM will be a Central Office staff member. The CIM will be responsible for oversight of transition activities, including ensuring effective communication and planning with residents at Glenwood, their Authorized Representatives, the IDT, and private providers about all aspects of an individual's transition and will address identified barriers to discharge. The CIM will have professional experience working in the field of IDD, and an understanding of best practices for providing community services to individuals with IDD. The CIM will also be responsible for identifying, evaluating, and addressing barriers to discharge. The CIM will provide oversight, guidance, and technical assistance to the IDTs by identifying strategies for addressing or overcoming barriers to discharge, ensuring that IDTs follow the processes described in this Agreement, and identifying and developing corrective actions, including the need for any additional training or involvement of supervisory staff. By the Effective Date, and until the position is filled, the State will designate a Central Office staff member with the appropriate experience to fulfill the CIM's duties. The CIM position will be filled within six months of the Effective Date.

202. The CIM shall be engaged in addressing barriers to discharge, including in all of the following circumstances:

a. The IDT is having difficulty identifying or locating a particular type of community placement, services and supports for an individual within 60 days of development of a discharge plan.

b. The IDT cannot agree on a discharge plan outcome within 30 days of the annual ISP meeting, or within 60 days after the admission to the Resource Center.

c. The individual or his or her Authorized Representative opposes discharge after all the requirements described in Section H.i-ii have been satisfied or refuses to participate in the discharge planning process.

d. The individual is not discharged within three months of selecting a provider.

e. The IDT recommends that an individual remain at Glenwood.

f. An individual is readmitted to Glenwood.

203. If an IDT recommends maintaining a placement at Glenwood or placing an individual in a congregate setting with five or more individuals, it shall document in the discharge plan the decision, the barriers to placement in a more integrated setting, and the steps the team will take to address the barriers. If the individual remains at Glenwood, an assessment by the IDT and the CIM will be performed at 6-month intervals from the decision for the individual to remain at the Glenwood, to ensure that the individual is in the most integrated setting appropriate to his or her needs.

204. No resident shall remain at Glenwood or be placed in another congregate setting with five or more individuals unless such placement is consistent with the individual's needs and informed choice and has been reviewed by the CIM.

205. Paragraph 204 shall not prevent the State from transferring residents to Woodward Resource Center, provided that no resident shall be transferred unless they have been offered a meaningful choice of community providers consistent with their identified needs and preferences, and have made an informed choice to continue receiving services in a Resource Center. If, at any point over the course of this Agreement, more than 50 members of the Target Population (approximately one third of the Glenwood census as of the Effective Date) are residing at Woodward, the terms of this Agreement shall apply to both Resource Centers.

206. The State shall produce routine public reports or maintain current public data dashboards regarding the status of Glenwood's community integration efforts, including historical data reflecting by month: the proportion of residents in each stage of transition planning, the number of transitions accomplished, and the types of placements, and recommendations that individuals remain at Glenwood.

207. The State shall ensure that information about barriers to discharge from involved providers, IDT members, and individuals' ISPs is collected from Glenwood and is aggregated and analyzed for ongoing quality improvement, discharge planning, and development of community-based services.

208. The State shall develop and implement quality assurance processes to ensure that ISPs, discharge plans, and transition plans are developed and implemented, in a documented manner, consistent with the terms of this Agreement. These quality assurance processes shall be sufficient to show whether the objectives of this Agreement are being advanced. Whenever problems are identified, the State shall develop and implement plans to remedy the problems.

209. A GRC staff member shall conduct monitoring visits within each of four (4) intervals (approximately seven, 30, 60, and 90 days) following an individual's transition. Documentation of the monitoring visit will be made using a standard checklist that encompasses all areas of the transition plan and addresses whether all supports and services are in place according to the timeframes in Paragraph 200. This review shall include ensuring that the new provider has a current person-centered individual support plan in place, consistent with the requirements in Paragraph 183. The State shall ensure staff conducting this monitoring are adequately trained and shall assess a reasonable sample of monitoring visits to ensure the reliability of the process.

210. The State shall provide ongoing community case management to members of the Target Population who transition to the community.

a. For individuals receiving case management services pursuant to this Agreement, the individual's case manager shall meet with the individual face-to-face on a regular basis and shall conduct regular visits to the individual's residence, as dictated by the individual's needs and preferences. The individual's case manager shall meet with the individual face-to-face at least every 30 days, and at least one such visit every two months must be in the individual's place of residence.

b. At these face-to-face meetings, the case manager shall: observe the individual and the individual's environment to assess for previously unidentified risks, injuries, needs, or other changes in status; assess the status of previously identified risks, injuries, needs, or other change in status; assess whether the individual's support plan is being implemented appropriately and remains appropriate for the individual; and ascertain whether supports and services are being implemented consistent with the individual's strengths and preferences and in the most integrated setting appropriate to the individual's needs. If any of these observations or assessments identifies an unidentified or inadequately addressed risk, injury, need, or change in status; a deficiency in the individual's support plan or its implementation; or a discrepancy between the implementation of supports and services and the individual's strengths and preferences, then the case manager

shall report and document the issue, convene the individual's service planning team to address it, and document its resolution.

211. The State shall develop and implement a system to identify and monitor individuals in the Target Population who transition from Glenwood Resource Center (for at least 365 days following transition) to another placement in order to: ensure health and safety; ensure a current support plan is in place consistent with the requirements in Paragraph 183; ensure whether supports identified in the individual's transition plan and current support plan are in place and achieving outcomes that promote their social, professional, and educational growth and independence in the most integrated settings; identify any gaps in care; and address proactively any such gaps to reduce the risk of readmission, crises, or other negative outcomes. The monitoring system shall include both face-to-face meetings with individuals in the Target Population and tracking by service utilization and other data.

I. State Staff

212. Glenwood shall maintain appropriate and adequate staffing, including by ensuring:

a. Retention of sufficient residential treatment workers per resident to safely staff GRC at all times. When determining how many residential treatment workers are needed, GRC shall use a relief factor multiplier formula of 1.8 (meaning there will be 1.8 residential treatment workers filled and budgeted for every residential treatment worker needed on shift) or more if necessary to account for staff vacancies and leave;

b. Retention of an adequate number of supervisory staff, and GRC leadership to sufficiently and safely staff GRC at all times;

c. Retention of demonstrably competent, appropriately trained and credentialed, staff and facility leadership in sufficient numbers to ensure GRC residents' safety and well-being and to comply with the mandates of this agreement, GRC and HHS policies and procedures, and current generally accepted professional standards of care;

d. Staff responsibilities and workloads are appropriate.

213. Within six months of the Effective Date, Glenwood shall develop and implement a reliable performance evaluation process for all GRC staff, providing for, at a minimum, comprehensive evaluations of each GRC staff member conducted at least annually by someone competent to reliably assess that staff member's performance. The State and the United States may agree to exclude certain individual staff members, or certain categories of staff members, from this requirement. When the GRC staff member to be evaluated is responsible for the delivery or supervision of clinical services, the evaluation of the quality of the GRC staff member's clinical care must be conducted by, or be informed by input from, a licensed professional of the same specialty.

214. The State shall ensure that complaints about the conduct of Glenwood staff are investigated to ensure that the complaints genuinely relate to staff performance or quality of care, and that discipline and other adverse employment actions are taken on the basis of performance or quality of care only. No adverse employment actions shall be taken for improper purposes such as retaliation or intimidation.

215. The State shall ensure that HHS Central Office conducts a timely review of the hiring and firing and discipline of GRC Leadership, including review of the relevant documentation. No hiring, firing, or discipline of GRC Leadership shall occur without approval from HHS Central Office.

J. Organizational Accountability

216. The State shall define the role and responsibility of an administrative position in HHS Central Office with the full responsibility to oversee the operations at GRC and with the authority to take appropriate action to improve services and remediate problems. The position shall have full authority over all aspects of GRC, including policy development, program design, personnel actions, and quality management, and shall be supported by appropriate staff members with the competence and resources to conduct this oversight through routine, comprehensive, and reliable evaluations.

217. The State shall conduct the oversight necessary to ensure compliance with each provision of this Agreement and with HHS and GRC policies. The State, through HHS Central Office, shall supervise and monitor GRC services, supports, and residents; ensure full and accurate reporting of, and response to, relevant trends and concerns; and ensure the identification and resolution of necessary corrective actions. The HHS Director shall receive reliable information, including through routine briefings, regarding these activities.

218. Early on and throughout the planning and implementation process, the State shall engage with stakeholders (including staff, parents, guardians, non-governmental entities with oversight responsibilities for GRC, and other stakeholders) to identify their goals, concerns, and recommendations regarding implementation of this Agreement. This shall include establishing mechanisms for regularly sharing with, and receiving information from, these stakeholders. The State shall conduct meetings at least semi-annually to discuss implementation, the public reporting referenced in Paragraph 226, and any actions to be taken in response.

219. HHS Central Office shall conduct regular in-person visits, engaging with persons served, guardians, and staff at various levels within the organization, with the goal of establishing multiple points of contact and sources of information.

220. The State shall develop, and train staff on, effective reporting policies and procedures that enable staff to report concerns, including at least one anonymous mechanism, without experiencing retaliation.

221. The State shall implement timely and effective investigations into reported concerns. The results of the investigations shall be provided to the Superintendent and HHS Central Office.

222. The State shall provide reporting GRC staff with a substantive response concerning the outcome of the investigation of the issues reported by the staff where legally permissible and not related to a confidential personnel action.

223. The State shall ensure that GRC and HHS Central Office develop and implement effective mechanisms for identifying, tracking, and addressing trends regarding resident care and health outcomes.

224. The State shall establish reliable measures to evaluate GRC's organizational accountability for resident well-being, and shall ensure regular reporting, analysis and, when necessary, corrective actions by GRC and HHS Central Office.

225. The State shall establish a Resident Council to enable GRC residents to make recommendations and provide information to the GRC Superintendent and the HHS Central Office administrator supervising the Superintendent regarding any topic the Council chooses to elevate. The State shall keep minutes of the Resident Council and provide those minutes to the Quality Council for the identification of necessary action steps.

226. Within one year of the Effective Date, the State shall establish reliable public reporting at least every six months, on the HHS website. The public reporting shall include the Quality Management reporting produced pursuant to Section IV.K below.

227. The State shall review GRC's policies to ensure they conform to the requirements of this Agreement and are implemented. The State shall update policies as needed.

228. HHS Central Office shall review and approve all policies, and amendments to them.

K. Effective Quality Management

229. The State shall implement reliable Quality Management processes and procedures consistent with current, generally accepted professional standards of care. Such processes shall timely and effectively detect problems with the provision of protections, services and supports; and ensure appropriate corrective steps are implemented.

230. The State shall maintain a Quality Management program that effectively collects and evaluates valid and reliable data, including data pertaining to the domains and topics identified in Paragraphs 211 and 231, sufficient to implement an effective continuous quality improvement cycle as set forth below. The Quality Management program shall use this data in a continuous quality improvement cycle to:

a. Develop sufficient reliable measures relating to the domains and topics identified in Paragraphs 211 and 231, with corresponding goals and timelines for expected positive outcomes, and triggers for negative outcomes;

b. Produce routine, valid and reliable reporting on the defined measures and related trends;

c. Identify significant trends, patterns, strengths, and problems at the individual and systemic levels;

d. Implement preventative, corrective, and improvement actions to address identified trends, patterns, strengths, and problems; and

e. Track the effectiveness of preventative, corrective, and improvement actions, and adjust such actions as needed if they do not result in expected prevention, correction, or improvement.

231. The Quality Management program shall collect, report on, and analyze valid and reliable data regarding GRC sufficient to identify overall trends in the following domains:

a. safety and freedom from harm (including neglect and abuse, exploitation, injuries, critical incidents, and deaths; timely reporting, investigation, and resolution of incidents);

b. physical health and well-being (including medication management; disease and wound management; admissions to emergency rooms or hospitals; incidence of physical health crises; occurrences of pneumonia; occurrences of pressure ulcers; accurate receipt of medication as prescribed; and access to and receipt of timely preventative, chronic, and acute healthcare and interventions – particularly interventions in response to changes in status);

c. behavioral health and well-being (including use of physical, mechanical, chemical, or medical restraints, use of restrictive interventions, incidents of behavioral health crises, and incidents of aggression);

d. engagement and skill acquisition;

e. choice and self-determination (including individual service plans developed through a person-centered planning process, inclusion of the resident in the planning process, individualized goals, self-direction of services, and meaningful and informed choices regarding community-based services and providers);

f. community inclusion (including community activities, integrated day and employment, educational opportunities, and relationships with non-paid individuals);

g. risk management (including risk thresholds and triggers);

h. staff capacity (including caseloads by discipline, training, staff turnover, and competency);

i. compliance with policies and procedures (including timely incident reporting and investigation, and timely provision of appropriate medical care);

j. referral to, admission and readmission to, diversion from, and length of stay in GRC; discharges and transitions from GRC and related planning; and barriers to serving individuals in more integrated settings.

232. The Quality Management program shall ensure that each IDT utilizes this continuous quality improvement information to track and trend the measures and triggers regarding resident outcomes, and to effectively identify, assess, and appropriately respond to positive and negative outcomes at the individual level.

233. HHS Central Office shall receive and review routine, valid and reliable Quality Management reporting regarding the domains described above, and related trends; notification of complaints regarding resident well-being and staff relations, and related trends; and other relevant reporting regarding GRC and the Target Population. This shall include a review of the information described in Paragraph 211.

234. HHS Central Office shall routinely monitor the quality and effectiveness of GRC's Quality Management program and take action to improve the Quality Management program when necessary.

235. The State shall effectively identify the need for, and shall direct and monitor the implementation and effectiveness of needed corrective actions and performance improvement initiatives at GRC.

V. Monitor

236. The Parties agree that a Monitor will be appointed to assess and report whether the provisions of the Agreement have been implemented and to provide technical assistance to help the State comply with its obligations under the Agreement. The Parties agree to file a joint motion asking the Court to appoint the Monitor. The Monitor may hire consultants and staff as necessary to assist in carrying out these duties. In addition, the Parties anticipate that responsibilities for monitoring may be divided among a number of experts. Funding for work by these personnel or entities will come out of the Monitor's budget. The Monitor shall select the experts, subject to the Parties' agreement. If the Parties cannot agree regarding the selection of an expert, the Monitor shall submit names to the Court for consideration and the Court shall determine whether to appoint an expert and, if so, select the expert.

237. The Monitor will be appointed for a period of three years from the Effective Date, subject to an evaluation by the Court to determine whether to renew the Monitor's appointment until the termination of this Agreement. In evaluating the Monitor, the Court will consider the Monitor's performance under this Agreement, including whether the Monitor is completing his or her work in a cost-effective manner and on budget, and is working effectively with the Parties to facilitate the State's efforts to comply with the Agreement's terms, including by providing technical assistance to the State. The Monitor may be removed for good cause by the Court at any time, on motion by any of the Parties which shall be granted for good cause shown, or the Court's own determination.

238. The Parties recognize the importance of ensuring that the fees and costs of monitoring the Agreement are reasonable. The Monitor will submit a proposed budget annually to the parties for comment, and to the Court for approval.

a. The Monitor shall submit monthly invoices to the State, and the State will pay the Monitor's invoices promptly. If the State disputes the invoice, the State may raise the concern by motion and the Court will rule on the appropriateness of the charge before payment is due.

b. The Court retains the authority to resolve any dispute that may arise regarding the reasonableness of fees and costs charged by the Monitor.

239. The Monitor shall only have the duties, responsibilities, and authority conferred by this Agreement. The Monitor shall be subject to the supervision and orders of the Court.

240. The Monitor shall conduct compliance reviews. The purpose of the compliance reviews is to determine compliance with the material requirements of this Agreement. Compliance reviews shall be conducted in a reliable manner based on accepted means and methods and shall set forth the basis for the Monitors' conclusions. The Monitor shall provide a verbal report of impressions following each on-site review and engage in collaborative problem-solving with the State.

241. Neither the State, the United States, nor any of their staff or agents shall have any supervisory authority over the Monitor's activities, reports, findings, or recommendations.

242. The Monitor may contract or consult with other persons or entities to assist in the evaluation of compliance. The Monitor shall pay for the services out of his or her budget. The Monitor is ultimately responsible for any compliance assessments made under this Agreement.

243. At the Monitor's discretion, the Monitoring Team (including the Monitor, subject matter experts, consultants, and staff) shall be permitted to engage in ex parte communications with the State and the United States regarding this Agreement. At the Monitor's discretion, the Monitoring Team may also have ex parte communications with the Court, only upon the Court's request or with the consent of the Parties. Members of the Monitoring Team shall not be required to disclose such communications, communications within the Monitoring Team, or draft or other internal work product, unless there is a substantial need as determined by the Court.

244. In the event the Monitor is no longer able to perform his or her functions or is removed, within 60 days thereof, the Parties shall together select and advise the Court of the selection of a replacement Monitor, acceptable to both. If the Parties are unable to agree on a Monitor, each Party shall submit the names of up to two candidates, along with the resumes and cost proposals, to the Court, and the Court will select and appoint from among the qualified candidates.

245. Should a Party to this Agreement determine that the Monitor has exceeded his or her authority or failed to satisfactorily perform the duties required by the Agreement, the Party

may petition the Court for such relief as the Court deems appropriate, including replacement of the Monitor, and/or any individual agents, employees, or independent contractors retained in this matter by the Monitor ("Monitoring Team Member"). In addition, the Court, on its own initiative and in its sole discretion, may replace the Monitor or any Monitoring Team Member for failure to adequately perform the duties required by this Agreement.

246. The Monitor and the United States (and its agents) shall have full access to persons, staff, facilities, buildings, programs, services, documents, data, records, materials, and things that are necessary to assess the State's progress and implementation efforts with this Agreement. However, the United States shall coordinate its access with the Monitor's as much as feasible to limit duplication of effort and burden on the State. Access shall include departmental or individual medical and other records. This access shall extend to individuals who move from Glenwood to any other setting, for one year from the date of the move, for the purpose of confirming that the transfer does not violate the federal rights of those former Glenwood residents and that they are receiving the necessary supports and services in that alternative setting. The State shall comply with reasonable requests by the Monitor or the United States (and its agents) to speak with State staff outside the presence of attorneys for the State and/or outside the presence of persons within the staff's supervisory chain. The United States and/or the Monitor shall provide reasonable notice of any visit or inspection or request for access. Reasonable notice shall include a list of persons or topics to be addressed. All requests for documents must be presented to counsel or the designated point of contact. All document requests shall allow a 30-day period for production. However, advance notice and a 30-day document production period shall not be required if the Monitor or the United States has a reasonable belief that a Glenwood resident faces a risk of immediate and serious harm. Access is not intended, and shall not be construed, as a waiver, in litigation with third parties, of any applicable statutory or common law privilege associated with information disclosed to the Monitor or the United States under this paragraph.

247. In completing his or her responsibilities, the Monitor may require written responses and data from the State concerning compliance.

A. Monitoring Plan and Tool

248. Within 90 days of the Monitor's selection the Monitor shall develop a draft monitoring plan and tool, to include outcome measures by which the Monitor will measure compliance. Compliance will be measured in part through a Quality Service Review (QSR) model.

a. The State and the United States shall both have 21 days to offer comments on the monitoring tool.

b. The Monitor shall consider all comments and issue a final Monitoring Plan and Monitoring Tool within 21 days of receiving the Parties' comments.

c. As necessary, the Parties and the Monitor may agree to amend and revise the Monitoring Plan and Monitoring Tool throughout the period of this Agreement.

B. Monitor Reports

249. Within 60 days of the Effective Date, the Monitor shall conduct a baseline review of Glenwood to become familiar with Glenwood and this Agreement.

250. Within 120 days of the Effective Date, the Monitor shall provide his or her preliminary observations and recommendations in a baseline Monitoring Report (which will follow the same draft and comment process as in Paragraph 251).

251. The Monitor shall both conduct a review and issue a Monitoring Report no later than six months after the baseline Monitoring Report, and every six months thereafter. A draft Report shall be provided to the State and the United States in draft form for comment at least 30 days prior to its issuance. Prior to issuing each Monitoring report, at a reasonable time designated by the Parties, the Monitor shall provide the Parties with verbal impressions based on each review, unless the Parties agree otherwise. The State and the United States shall provide comments, if any, to the Monitor within 15 days of receipt of the draft Report. The Monitor shall consider the responses of the State and the United States and make appropriate changes, if any, before issuing the final Report.

252. The Monitoring Reports shall describe the steps taken by the State to implement this Agreement and shall evaluate the extent to which the State has complied with each substantive provision of the Agreement. Each Monitoring Report:

a. Shall evaluate the status of compliance for each relevant provision of the Agreement using the following standards: (1) Substantial Compliance; (2) Partial Compliance and (3) Non-compliance. The Monitor shall review a sufficient number of pertinent documents and interview or observe a sufficient number of staff and residents to accurately assess current conditions. The Monitor may also communicate with Glenwood residents and former residents, family members, and relevant community members to assist the Monitor's assessment of current conditions;

b. Shall describe the steps taken by each member of the monitoring team to analyze conditions and assess compliance, including documents reviewed and individuals interviewed or observed, and the factual basis for each of the Monitor's findings;

c. Shall contain the Monitor's independent verification of representations from the State regarding progress toward compliance, and examination of supporting documentation; and

d. May provide recommendations for each of the provisions in the Agreement outlining proposed actions for at least the next six months for the State to complete toward achieving compliance with the particular provision.

253. These Monitoring Reports shall be filed with the Court and shall be written with due regard for the privacy interests of Glenwood residents. The Monitoring Reports provide relevant evidence regarding compliance. Accordingly, information in the Monitoring

reports will be considered persuasive, but rebuttable, in any court proceeding regarding this Agreement. The State shall publish the Monitoring Reports on the HHS website.

254. Nothing in this Section prohibits the Monitor from issuing interim letters or reports to the United States, the State or the Court via the public record in this case, should he or she deem it necessary.

C. Monitor's Relationship with Others

255. In completing his or her responsibilities, the Monitor may testify in enforcement proceedings regarding any matter relating to the implementation, enforcement, or dissolution of the Agreement, including, but not limited to, the Monitor's observations, findings, and recommendations in this matter.

256. The Monitor, and any staff or consultants retained by the Monitor, shall not:

a. Be liable for any claim, lawsuit, or demand arising out of their activities under this Agreement (this paragraph does not apply to any proceeding for payment under contracts into which they have entered in connection with their work under the Agreement);

b. Be subject to formal discovery in any litigation involving the services or provisions reviewed in this Agreement, including deposition(s), request(s) for documents, and request(s) for admissions, interrogatories, or other disclosure;

c. Testify in any other litigation or proceeding with regard to any act or omission of the State or any of the State's agents, representatives, or employees related to this Agreement, nor testify regarding any matter or subject that he or she may have learned as a result of his or her performance under this Agreement, nor serve as a non-testifying expert regarding any facts that he or she may have learned as a result of his or her performance under this Agreement.

257. The State and the United States shall not otherwise employ, retain, or be affiliated with the Monitor, or professionals retained by the Monitor while this Agreement is in effect, and for a period of at least one year from the date this Agreement terminates, unless the other Party gives its written consent to waive this prohibition.

258. If the Monitor resigns from his or her position as Monitor, the former Monitor may not enter any contract with the State or the United States on a matter encompassed by this Agreement without the written consent of the other Party while this Agreement remains in effect.

VI. Implementation

259. Within 30 days of the Effective Date, the State shall designate an Agreement Coordinator to coordinate compliance with this Agreement and to serve as a point of contact for the Parties and the Monitor.

260. The State shall create an annual Implementation Plan that describes the actions it will take to fulfill its obligations under this Agreement. Implementation of this Agreement shall be completed in phases as outlined in the Agreement and the Implementation Plan. Within 90 days of the Effective Date, the State shall provide the first Implementation Plan ("Implementation Plan #1") to the United States and the Monitor. The United States and the Monitor shall have an opportunity to review and comment on each annual Implementation Plan before it is finalized.

261. In its Implementation Plan, the State shall: (1) identify the issues to be addressed that year, and, for each issue: the planned actions; the persons or positions responsible; the resources needed; the target completion date; a completion status measure; and expected outcome; (2) a general forecast of issues to be addressed in successive years; and (3) beginning with Implementation Plan #2, an assessment of what worked and what should be adjusted in the previous plan's implementation. In Implementation Plan #1, the State shall address at least: clinical care; client rights and protections; and community integration. Over time, the Implementation Plans shall address the issue areas subject to the public reporting required in Paragraph 226, above.

262. The United States and the Monitor may provide comments regarding the Implementation Plan (and any further Implementation Plans) within 30 days of receipt. The State shall timely revise its Implementation Plans to address comments from the United States and the Monitor.

263. The Parties and the Monitor shall meet and consult at least monthly during the first year of this Agreement and at least quarterly thereafter.

264. Annually, the State, in conjunction with the United States and the Monitor, shall supplement the Implementation Plan to focus on and provide additional detail regarding implementation activities. The State shall address in its further Implementation Plans any areas of non-compliance or other recommendations identified by the Monitor in his or her reports.

265. The State shall make the Implementation Plan publicly available, including by posting the Plan, and its supplements, on the State's website.

VII. Enforcement

266. The State of Iowa is responsible for ensuring compliance with the provisions of this Agreement.

267. The United States District Court for the Southern District of Iowa will retain jurisdiction over this matter for the purposes of enforcing this Agreement as an order of the Court.

268. During the period that the Agreement is in force, the parties shall move for a status conference with the Court at least semi-annually to update the Court on the State's compliance with this Agreement. Either party may file these motions.

269. During the period that the Agreement is in force, if the United States determines that the State has not made material progress toward substantial compliance with an obligation under the Agreement, the United States may initiate enforcement proceedings against the State in Court for an alleged failure to fulfill its obligation under this Agreement.

270. Prior to taking judicial action to initiate enforcement proceedings, the United States shall give the State written notice of its intent to initiate such proceedings, and the parties will engage in good-faith discussions to resolve the dispute.

271. The State shall have 30 days from the date of such notice to cure the failure (or such additional time as is reasonable due to the nature of the issue and agreed upon by the parties) and provide the United States with sufficient proof of its cure. At the end of the 30-day period (or such additional time as is reasonable due to the nature of the issue and agreed upon by the United States), in the event that the United States determines that the failure has not been cured or that adequate remedial measures have not occurred, the United States may initiate contempt proceedings without further notice. The United States commits to work in good faith with the State to avoid enforcement actions. The State retains all available defenses against such actions, including moving to modify the terms of the consent decree.

272. In case of an emergency posing an immediate threat to the health or safety of any GRC resident or staff member, however, the United States may omit the notice and cure requirements herein and seek enforcement of the Agreement.

VIII. Termination

273. Except where otherwise agreed to under a specific provision of this Agreement, the State will have achieved:

a. Substantial compliance with all provisions in Section IV.A (Research) by the Effective Date;

b. Substantial compliance with all provisions in Sections IV.B (Integrated Interdisciplinary Care and Services) and IV.H (Individual Support Planning, Discharge Planning, and Transition Planning from the Resource Centers) of this Agreement within six months of the Effective Date;

c. Tangible progress in achieving substantial compliance with at least the following sections of this Agreement within one year of the Effective Date: IV.C (Clinical Care); IV.D (Restrictive Interventions); and IV.G (Incident Management);

d. Substantial compliance with all provisions of this Agreement within two years of the Effective Date, unless an earlier date is specified above.

274. This Agreement shall terminate in five years if the Parties agree that the State has attained substantial compliance with all provisions and maintained that compliance for a period of one year.

275. The State may seek termination of any substantive section (i.e. any capitalized section tabbed on the far left of the Agreement, such as "Clinical Care," "Restraints," "Recordkeeping," etc.) by filing with the Court a motion to terminate that section. The burden will be on the State to demonstrate that it has attained and maintained its substantial compliance as to that section for at least one year, or that circumstances have made compliance with that section irrelevant.

276. The burden will be on the State to demonstrate that it has maintained substantial compliance with each of the provisions of this Agreement. Non-compliance with mere technicalities, or temporary failure to comply during a period of otherwise sustained compliance, will not constitute failure by the State to maintain substantial compliance. At the same time, temporary compliance during a period of sustained non-compliance will not constitute substantial compliance.

277. The burden will be on the State to demonstrate it has achieved substantial compliance with a particular section of this Agreement.

278. Regardless of this Agreement's specific requirements, this Agreement will terminate, or substantive sections as described in Paragraph 275 may terminate, upon a showing by the State that it has come into durable compliance with the requirements of the Constitution that gave rise to this Agreement. In order to demonstrate durable compliance, the State must establish with the Court that it is operating in accordance with these requirements and has been doing so continuously for one year.

279. Should any provision of this Agreement be declared or determined by any court to be illegal, invalid, or unenforceable, the validity of the remaining parts, terms, or provisions will not be affected. The Parties shall not, individually or in combination with another, seek to have any court declare or determine that any provision of this Agreement is invalid.

280. The Parties agree to work collaboratively to achieve the purpose of this Agreement. In the event of any dispute over the language, requirements or construction of this Agreement, the Parties agree to meet and confer in an effort to achieve a mutually agreeable resolution.

281. This Agreement shall constitute the entire integrated agreement of the Parties.

282. Any modification of this Agreement shall be executed in writing by the Parties, shall be filed with the Court, and shall not be effective until the Court enters the modified agreement and retains jurisdiction to enforce it.

IX. General Provisions

283. Interpretation of this Agreement shall be governed by the following rule of construction: "including" means including without limitation, unless otherwise specified.

284. The State shall coordinate with or enter into Memoranda of Understanding or other contractual arrangements with all appropriate agencies and State vendors in order for the State to comply with provisions of this Agreement.

285. The United States and the State shall each bear the cost of their own fees and expenses incurred in connection with this case.

286. All services mentioned or described in this Agreement are subject to reasonableness standards and nothing herein shall be interpreted to mean that the provision of services is unlimited in amount, duration or scope.

287. The Agreement is binding on all successors, assignees, employees, agents, contractors, and all others working for or on behalf of the State to implement the terms of this Agreement.

288. The Parties agree that, as of the Effective Date of this Agreement, litigation is not "reasonably foreseeable" concerning the matters described in this Agreement. To the extent that any Party previously implemented a litigation hold to preserve documents, electronically stored information, or things related to the matters described in this Agreement, the Party is no longer required to maintain such a litigation hold. Nothing in this paragraph relieves any Party of any other obligations imposed by this Agreement, including the document creation and retention requirements described herein.

289. The State shall not retaliate against any person because that person has filed or may file a complaint, provided assistance or information, or participated in any other manner in the United States' investigation or the Monitor's activities related to this Agreement. The State shall implement reasonable procedures to detect and prevent any acts of retaliation. The State shall timely and thoroughly investigate any allegations of retaliation in violation of this Agreement and take any necessary corrective actions identified through such investigations.

290. Failure by any Party to enforce this entire Agreement or any provision thereof with respect to any deadline or any other provision herein will not be construed as a waiver, including of its right to enforce other deadlines and provisions of this Agreement.

291. The Parties shall promptly notify each other of any court or administrative challenge to this Agreement or any portion thereof.

292. The Parties represent and acknowledge this Agreement is the result of extensive, thorough, and good faith negotiations. The Parties further represent and acknowledge that the terms of this Agreement have been voluntarily accepted, after consultation with counsel, for the purpose of making a full and final compromise and settlement of the allegations set forth in the Department of Justice's CRIPA Notice dated December 22, 2020. Each Party to this Agreement represents and warrants that the person who has signed this Agreement on behalf of a Party is duly authorized to enter into this Agreement and to bind that Party to the terms and conditions of this Agreement.

293. This Agreement may be executed in counterparts, each of which will be deemed an original, and the counterparts will together constitute one and the same Agreement, notwithstanding that each Party is not a signatory to the original or the same counterpart.

294. The performance of this Agreement shall begin immediately upon the Effective Date.

295. The State shall maintain sufficient records and data to document that the requirements of this Agreement are being properly implemented and shall make such records available to the Monitor and the United States for inspection and copying on a reasonable basis. All requests for documents shall allow a 30-day period for production, except where the Monitor or the United States has a reasonable belief that a member of the Target Population faces a risk of immediate and serious harm. Such action is not intended, and shall not be construed, as a waiver, in litigation with third parties, of any applicable statutory or common law privilege associated with such information. Other than to carry out the express functions as set forth herein, both the United States and the Monitor shall hold such information in strict confidence to the greatest extent possible.

296. "Notice" under this Agreement shall be provided by email to the signatories below or their successors.

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FOR THE UNITED STATES:

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So ordered this _____ day of _____, _____.

_____
United States District Court Judge

Attachment D

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF IOWA
CENTRAL DIVISION

UNITED STATES OF AMERICA, Plaintiff, v. STATE OF IOWA, Defendant.	Civil Case No. **ORDER GRANTING JOINT MOTION FOR ENTRY OF CONSENT DECREE**

The Court has before it the Joint Motion for Entry of Consent Decree. Upon consideration of the Memorandum of Law in Support of Joint Motion for Entry of Consent Decree, it is on this ____ day of _____, 2022, hereby ORDERED that

1. The Joint Motion for Entry of Consent Decree is GRANTED;
2. The Court will enter the Agreement attached to the Joint Motion as a separate Order of the Court ("Consent Decree"); and
3. The Clerk of the Court shall enter the Consent Decree as a separate docket entry.

_____
HON.
UNITED STATES DISTRICT JUDGE