Case No. 18-15242

# UNITED STATES COURT OF APPEALS

for the

# **NINTH CIRCUIT**

# AMERICAN DIABETES ASSOCIATION Plaintiff-Appellant,

V.

UNITED STATES DEPARTMENT OF THE ARMY, et al. *Defendants-Respondents*.

Appeal from the Judgment of the United States District Court for the Northern District of California
Case No. 5:16-cv-04051-LHK
Hon. Lucy H. Koh

## AMICUS CURIAE BRIEF ON BEHALF OF THE PEDIATRIC DIABETES COMMUNITY

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#### I. CONSENT FOR AMICUS BRIEF

Pursuant to Fed. R. App. P. 29(a), all parties to this case consent to the filing of this *Amicus Curiae* Brief.

# II. STATEMENT OF PARTICIPATION REQUIRED BY FED. R. APP. P. 29(A)(4)(E)

No party's counsel authored this brief in whole or in part. No party, party's counsel, or other person contributed money to fund preparing or submitting this brief.

#### III. CORPORATE DISCLOSURE STATEMENT

Pursuant to Rule 26.1 of the Federal Rules of Appellate Procedure, Amici American Association of Diabetes Educators, Children with Diabetes, Endocrine Society, International Society for Pediatric and Adolescent Diabetes, Pediatric Endocrine Society and Type 1 Diabetes Exchange each states that it does not have a parent corporation and that no publicly held companies hold 10% or more of its stock.

#### IV. STATEMENT OF INTEREST OF AMICI CURIAE

Each of the Amici in this case is committed to the proper care and management of children with diabetes. For convenience these Amici will be referred to as either the "pediatric diabetes community" or "Community."

The glossary for critical definitions for this brief includes:

"Endocrinology" is the medical specialty which focuses on the endocrine system. The pancreas is the organ in the endocrine system that produces insulin, which is necessary for human life. Insulin breaks down carbohydrates and converts them into energy, keeping blood sugar levels in an appropriate range. When the pancreas cannot produce any insulin or produces insufficient insulin, diabetes occurs.

"Diabetes" is a chronic and currently incurable disease. Untreated, it results in the abnormal metabolism of carbohydrates and elevated levels of glucose in the blood. Abnormal blood sugar leads to many acute and chronic symptoms, some of which can be life threatening. Such symptoms include frequent urination, unusual thirstiness, enhanced hunger, feeling listless, tired and fatigued, feeling highly irritable, blurred vision, slow healing of bruises and cuts, swollen, red and tender gums, tingling and numbness in hands and feet. Effects of diabetes include macrovascular (heart, brain and legs) complications and microvascular (eyes, kidneys, feet and nerves) complications. These complications lead to heart disease, kidney damage, retinopathy of the eyes, neuropathy, stroke, limb amputations and death. American children and adults die each year due to hyperglycemia (high blood sugar) which causes diabetic ketoacidosis (a life-threatening condition), and hypoglycemia (low blood sugar). However, adequate management of diabetes can

avoid or minimize all complications and effects. Today, there are more than 30 million children and adults with diabetes in the United States.

"Pediatric" broadly means any person under 18 years old. The children most in need of help to care and manage their diabetes are in preschool and elementary school age groups.

### A. American Association of Diabetes Educators

The American Association of Diabetes Educators has a membership of over 14,000. It is a multidisciplinary association of healthcare professionals (registered nurses, physicians, registered dieticians, psychologists, etc.) dedicated to the optimal health and wellness of all people with diabetes, including children. Its members "focus on teaching patients about diabetes and self-management techniques" for diabetes. This association is recognized for its expertise in the care and management of diabetes and in the development of clinical practice recommendations for the day-to-day treatment of diabetes.

#### B. Children with Diabetes

Children with Diabetes is an online community for kids, families and adults living with Type 1 Diabetes (formerly termed juvenile diabetes). It has participants in the tens of thousands. This community focuses on "care today, so we are ready for a cure tomorrow." As an advocate and resource, it provides support, education

and inspiration to empower families living with diabetes to enjoy healthy, enriched lives.

## C. Endocrine Society

The Endocrine Society is an international body with over 18,000 members from over 100 countries. It represents the full range of disciplines associated with the field of endocrinology. These professionals are dedicated to the research and treatment of endocrine disorders, including diabetes. Its mission is to "unite, lead, and grow the endocrine community to accelerate scientific breakthroughs and improve health worldwide." The Society is a world-renown scientific expert, publisher, educator and advocate in the field of endocrinology.

## D. International Society for Pediatric and Adolescent Diabetes

The International Society for Pediatric and Adolescent Diabetes has over 1,400 professional members and is an international organization whose purpose is to promote clinical and basic science, research, education and advocacy in childhood and adolescent diabetes. The goal of this society is "a better world for children and adolescents with all types of diabetes."

# E. Pediatric Endocrine Society

The Pediatric Endocrine Society has over 1200 members representing professionals who practice endocrinology. Its mission is "to advance and promote the endocrine health and wellbeing of children and adolescents." The Society is

dedicated to research and treatment of children with endocrine disorders, including diabetes.

#### F. Type 1 Diabetes (T1D) Exchange

The T1D Exchange is a consortium of major pediatric diabetes centers which facilitate patient-centered research. The Exchange has over 50,000 participants and seeks to inform and guide product development, drive better clinical care, and contribute to scientific discoveries that can lead to important breakthroughs. It includes over 82 pediatric diabetes clinics such as the Stanford University School of Medicine, Children's Hospital Los Angeles, the Harold Schnitzer Diabetes Health Center at Oregon Health and Science University, Yale Children's Diabetes Program, Joslin Diabetes Center, the Barbara Davis Center, Naomi Berri Diabetes Center at Columbia University, and Johns Hopkins University Pediatric Endocrinology.

#### V. SUMMARY OF ARGUMENT

The diabetes pediatric community strongly supports and urges the standing of the American Diabetes Association (ADA) in this case. The ADA is the most suitable organization to represent the best interests of children with diabetes in this case. The ADA has a widespread positive impact in the care and management of diabetes for children.

In this case, the Army's efforts regarding care for children with diabetes are not medically necessary or appropriate. These efforts discourage family access and participation by providing a limited scheme for child care which is unduly burdensome and medically inadequate. The Army requires families of children with diabetes to accommodate the Army rather than the Army accommodate the children, as is required by law. If the ADA does not have standing in this case, no other organization does.

#### VI. ARGUMENT

#### A. Introduction

The mission of the ADA is "to prevent and cure diabetes and to improve the lives of all people with diabetes." A life free of diabetes and all its burdens is the ADA vision. To that end, the ADA assists children and their families who face obstacles created by diabetes to obtain knowledge, care, education and the opportunity to thrive in the world alongside their peers who do not have diabetes.

The ADA is the only organization in the diabetes world which is both a medical society for those professionals who treat diabetes and a voluntary health agency for non-medical persons affected by diabetes. With more than 400,000 members (over 14,000 professional members and over 400,000 general members), the ADA is the largest, non-governmental organization in the world focusing on diabetes care and management in people's daily lives.

The impact of the ADA in the fight against diabetes can be felt on every corner in every community throughout the world. From backyards to schoolyards, from research laboratories to health care providers' offices, and from diagnosis to the end of life, the ADA fights to make sure that individuals, children and families have the knowledge and resources they need to fight diabetes and the obstacles that diabetes creates. The ADA answers the calls and provides valuable information to anyone who cares for and manages diabetes, regardless of membership.

- B. The ADA is at the center of the efforts to ensure the care, management and rights for children with diabetes.
  - 1. These Amici represent organizations whose members and participants provide care and management for children with diabetes.

These Amici represent a broad spectrum of organizations whose members provide care and management for children with diabetes throughout the world. *See supra* Part IV. Indeed, including the ADA, this pediatric diabetes community is the most authoritative and knowledgeable source for information about children with diabetes.

2. This pediatric diabetes community acknowledges the important role of the ADA for children with diabetes.

The community is participating in this case because it recognizes the important role the ADA plays in the fight against diabetes. The ADA's Standards of Medical Care in Diabetes Standards of Medical Care in Diabetes—2018, 41 DIABETES CARE S1 (2018), is the authoritative template for the care and

management of all people with diabetes, including the standards of medical care in diabetes for children and adolescents. *Id.* at 5126. See Exhibit 1 in Addendum. Additionally, and even more specifically, the ADA publishes two position statements regarding the "Care Of Young Children with Diabetes in the Child Care Setting" and "Diabetes Care in the School Setting". All of these standards and position statements are rigorously peer reviewed. They focus on the special and unique needs and issues for the care and management of children with diabetes. They apply to all children of every age, i.e. infants, toddlers, preschool, elementary and adolescent.

These standards and statements are recognized and relied on by the entire pediatric diabetes community. They are the foundation for the care and management of children with diabetes everywhere by anyone.

3. The ADA has a long historic role in its leadership regarding children with diabetes.

The ADA's role includes creating and maintaining medical standards of care, funding scientific research, and advocacy for children with diabetes. In advocacy, the ADA has negotiated many legal settlements and filed many lawsuits to protect the rights of children in both school and child care settings. No other

<sup>&</sup>lt;sup>1</sup> Linda Siminerio et al. Care of Young Children with Diabetes in the Child Care Setting: A Position Statement of the American Diabetes Association, 37 DIABETES CARE 2834 (2014). See Exhibit 2 in Addendum.

<sup>&</sup>lt;sup>2</sup> Crystal Jackson et al. *Diabetes Care in the School Setting: A Position Statement of the American Diabetes Association*, 38 DIABETES CARE 1958 (2015). See Exhibit 3 in Addendum.

organization has a larger, more durable commitment to these issues. As a result, the entire pediatric diabetes community often refers people to the ADA because of its commitment to help children with diabetes.

Starting in the late 1980s, the ADA has been involved in civil rights litigation to insure and protect the rights and remedies of children with diabetes.<sup>3</sup> Many of these cases involved the Department of Justice (DOJ).<sup>4</sup> In the mid-1990s, the ADA brought two lawsuits regarding the care and treatment of children with diabetes in a child care setting. *Davis v. La Petite Academy*, No. CV97-0083 (D. Ariz.1997); *Stuthard v. Kinder Care*, No. C2-96-0185 (S.D. Ohio1996). These two cases were particularly significant since, at the time, La Petite Academy and Kinder Care were the two largest child care providers in the United States. These settlements, Settlement Agreement Under the Americans with Disabilities Act

<sup>&</sup>lt;sup>3</sup> ADA involvement includes being *amicus curiae*, a party and consultant expert. Some of these many cases include: *R.K. v. Board of Education of Scott County*, 494 Fed. Appx. 589 (6th Cir. 2012); *K.C. v. O'Connell*, Case No. CV-04077-MMC, (N.D. Ca. 2005); *ANA v. O'Connell*, 57 Cal. 4th 570, 304 P3d 1038 (Cal. 2013).

<sup>&</sup>lt;sup>4</sup> Settlement Agreement Between The United States of America and Learning Care Group, Inc. (2018), available at https://www.justice.gov/opa/press-release/file/1044751/download; Settlement Agreement Between The United States of America and Philadelphia Freedom Valley YMCA (2016), available at https://www.ada.gov/rocky\_run\_sa.html; Settlement Agreement Between The United States of America and YMCA of metro Chicago Association (2016), available at https://www.ada.gov/ymca\_chicago.html; Settlement Agreement between The United States of America and Arlington-Mansfield Area YMCA (2016), available at https://www.ada.gov/arlington\_ymca.html; Settlement Agreement Between The United States of America and Rainbow River Child Development Center (2010), available at https://www.ada.gov/rainbow\_river/rainbow\_river\_sa.htm; Stipulated Settlement Agreement, Final Judgment, and Consent Order, E.M. v. Town Sports International, Inc., No. 05-10611 (D. Mass. Apr. 10, 2006).

Between the United States of America and La Petite Academy (Oct. 23, 1997), available at https://www.ada.gov/lapetite.htm; KinderCare Settlement Agreement, available at https://www.ada.gov/kinder1.htm, created the foundation for necessary diabetes care in the child care environment and led to the position statement regarding proper diabetes care in any child care setting.

For almost 10 years, the ADA was in litigation with the California Department of Education and the American Nurses Association concerning the care and treatment of children with diabetes in California schools. In 2013 the Supreme Court of California issued a unanimous decision in favor of the ADA, recognizing that trained, unlicensed staff were legally permitted to administer insulin to children in school. *American Nurses Association v. Torlakson*, 304 P.3d 1038 (Cal. 2013) See Exhibit 4 in Addendum.

Most significantly, the ADA created a Safe at School (SAS) program to help families, school systems, child care programs, camps and youth programs properly and safely care for children with diabetes. The SAS program involves education, negotiation, litigation and legislation. It provides advice, support, tips and tools on self-advocacy, referrals to both medical and legal help, training for healthcare professionals and attorneys, workshops for families, education for child care organizations and facilities. It also provides direct legal assistance through the Legal Advocate Program. It is a source of information, training and oversight for

schools, child care programs, nurses, and lay employees. SAS is in all 50 states, in many hundreds of child care facilities, and has secured legislation specific to pediatric diabetes protections in 33 states.

The Declaration of Sarah Fech-Baughman outlines the particular resources and efforts of the ADA regarding the care and management of pediatric diabetes by the Army. ER 028-036. This includes assisting at least 26 families to date and many hours of pro bono time. How much is enough to create standing? ADA efforts certainly should qualify for adequate standing in this case.

In short, for decades the ADA has committed substantial resources to the care and management of children with diabetes in child care facilities, impacting many tens of thousands of children. No one else can equal this commitment of resources to these pediatric diabetes issues. If the ADA, as the standard bearer for these children, has no organizational standing to represent the interests and protect their rights, who does?

# C. The care and management for children with diabetes must be complete, comprehensive and continuous.

Unfortunately, diabetes in children is growing astronomically. Children with diabetes have unique needs which relate to physical and psychosocial growth and variability. Diabetes management must be individualized for each child in order to work for different issues and particular needs. Preschool children usually cannot adequately manage their diabetes without adult help. Generally, the need for help

lessens as the child matures. The complex decision making for diabetes that management can require adult help even past adolescence.

Diabetes is currently incurable; it can only be managed. Prescription medications, diet, exercise and insulin are the components of that management. Diabetes management must be individualized for each child's different needs. These tools allow children to lead healthy and productive lives. Even as researchers are struggling to find a cure for diabetes, there is real world progress that has already been made, in terms of better management options, better insulin, better monitoring options and better medications.

The purpose of care and management is to allow a child to live as fully as a child who has no diabetes. Proper diabetes management today diminishes future diabetes complications, such as blindness, amputations and end stage renal disease. All of the current TV and online advertising about new diabetes medications highlights the changing world of diabetes care. For the ADA, the proper care for children with diabetes is, and has been for more than 30 years, an ironclad commitment. This includes insuring the proper care for children in any child care program. This is the goal for the ADA and the pediatric diabetes community represented in this brief. Hence the need for individualized management.

Generally, younger children with diabetes cannot manage their own diabetes without some adult oversight and supervision. Children become more and more

self-reliant as they grow and mature, but this timeline is unique to each child and varies greatly.

The burden on a family with a child with diabetes (particularly a young child) is enormous, demanding and continual. Diabetes is 24/7, with no vacation Diabetes is ever present, unforgiving and relentless. Families days or time off. strive to allow such children to live normal lives and to avoid the tragedies of complications both acute and chronic. In the short term, these families strive to assist the child in avoiding dangerous high and low blood sugar values, which can threaten a child's life. These families must balance food, exercise, sleep, medication and blood glucose monitoring. It is recommended that there be at least quarterly medical visits to confirm good management and make necessary adjustments. Throughout the maturing process, a child's needs for management of their diabetes changes. No one management plan fits everyone forever. Each child with diabetes must have an individualized management plan which changes as the child matures. The essence of care and management is that it be pursuant to a specific, individualized plan which is complete, comprehensive, and continuous.

To be "complete" means covering every aspect of life, including food, activity level, medication, school, child care, field trips and blood sugar management. This is of critical importance to children who manage diabetes with insulin, for their blood sugar level is the most critical element of good outcomes.

This monitoring covers them during all aspects of life everywhere they go and for whatever they do. A parent cannot allow a child to go to a birthday party where there will be cake or sweets without careful planning. There is no such thing as a babysitter without specific training on how to handle diabetes issues. Children with diabetes cannot go to a movie with friends without a plan which is complete, comprehensive, and continuous.

"Comprehensive" means that the child, the child's family, child care providers and others in the child's support network can appreciate the child's diabetes management and assist the child when necessary. Access to adequate care and supervision is critical and always necessary 24/7. Without this access, pediatric diabetes cannot be safely managed.

"Continuous" means regularly without breakdowns or interruptions in the plan. Flexibility is required within the parameters set by the child's medical providers. This requires constant decision making by the family. Although the diabetes management strategy is set by the medical providers, the tactics to implement belong to the child, the family and any child care provider. These management tactics are day-to-day, often hour-to-hour. Illness needs special diabetes management. Athletics can only happen with a thoughtful plan on how to supplement or restrict insulin use. Even a trip to McDonalds is dangerous without a plan to balance the food with additional insulin.

Sometimes, the day-to-day management by the family is interrupted by other family needs such as employment. The family is caught in the horrible vise of family medical needs versus family financial needs, frequently a no-win choice. Sometimes, parents must work and a child must be in a child care setting. These children with diabetes are entitled to the same opportunities as their peers who do not have diabetes.

The ADA created Standards of Care, Position Statements and the Safe at School program to educate all child caregivers. Such caregivers are not optional but rather essential to the well-being, safety and survival of the child and the family.

# D. Children with diabetes must have meaningful access to adequate care and management.

Access to timely care and management of diabetes is essential, particularly with insulin. Insulin is not a cure for diabetes. It only reduces blood sugar values and artificially mimics the actions of a normally functioning pancreas. Of course, when children take insulin, management cannot be as perfect as those of us with a normally functioning pancreas. This is because the human body absorbs insulin at differing rates, depending on age, physical condition, sickness and stress. Children with diabetes must handle this challenge, and usually need assistance. For example, a child who is playing on the playground doesn't realize that the insulin tubing for her pump is disconnected or the battery expired. Within hours, that

child can be in peril due to lack of insulin. Administration of insulin is the foundation of care for a child with Type 1 diabetes, but insulin has its own complications and issues.

Safe insulin use focuses on the absolute necessity for blood glucose monitoring. Such monitoring allows children to plan to have blood sugar levels in the therapeutic range established by the medical provider. Outside the therapeutic range the high or low blood sugar can create both acute and chronic medical problems which impair the safety of the child. Insulin must be balanced with food, activity, and other factors, such as illness. For each child with diabetes, there is an unrelenting need to strike this balance. Timelines for care and treatment are both essential and indispensable. If treatment is not medically timely, serious medical consequences follow from either too high or too low blood sugar.

The Army's approach to these children is to build in artificial delays, promote segregation of these children and avoid having these children in its child care programs. So, for example, the Army requirement of a lengthy approval process of 4 months means no safe care until insulin administration is allowed. Everyone in the pediatric diabetes community and all families with diabetes know by experience that insulin can be safely administered by trained non-medical people. Families, including parents, siblings, grandparents, aunts, uncles and cousins safely administer insulin. Neighbors, friends and babysitters safely provide

insulin to children. The California Supreme Court recognized that insulin administration can be reliable and safe from trained, unlicensed school staff. *American Nurses Association v. Torlakson*, 57 Cal 4<sup>th</sup> 570, 304 P.3d 1038 (Cal. 2013). See Exhibit 4 in Addendum.

The delays and uncertainties built into the Army approval process are not only unnecessary and logistically difficult, but medically dangerous. These delays (10 weeks for any accommodation approval and up to 4 months for insulin approval) are used to effectively ban children with diabetes from child care. The uncertainty created by these artificial and unwarranted delays makes it impossible for families to adequately plan, adjust and stay within its diabetes management plan. The Army, in effect, created a process which requires the family to accommodate the Army's barriers, instead of the Army working toward an accommodation that mainstreams these children instead of segregating them.

# E. The Army interferes with, burdens and undermines the necessary care and management of children with diabetes and segregates them from their peers.

The Army's conduct in this case demonstrates a persistent lack of understanding about diabetes and the necessary care of children with diabetes. A review of the six parent declarations, ER 037-042; ER 043-047; ER 048-057; ER 058-063; ER 064-069; ER 070-074, illustrates the impact of the Army's barriers and the inadequacies of its policies toward these children. These declarations show

loss of work, change of living location, change of work, multiple daily visits, lack of certainty about care and management, and general disruption of family and life activities. All of this is unnecessary and is caused solely by the Army's refusal to accommodate and work with these children and their families.

Not only does the Army establish unreasonable and unnecessary application and approval processes, but also impractical time delays, e.g. approximately 2 year delay for M.W. ER 041-042. The Army forces the families to accommodate the Army, by having them leave their jobs and relieve the Army of its responsibilities to the children in its care. The Army sidesteps its legal obligations through a process which is not in the least accommodating.

The alleged mission of these Army services is "to help Army families meet their parental challenges and maintain their mission readiness." US Army MWR, Child and Youth Services @ armymwr.com. For children with diabetes, the Army dramatically fails that test. As the family declarations show, the Army adds to the family trauma and problems of having a child with diabetes. See the 6 parent declarations about the additional family trauma and problems caused by the Army. ER 037-074. Its claim to make "life better for Army families" is a cruel hoax, for their policies force these children out of child care and away from their peers who do not have diabetes.

The negative impact on the child's exclusion from the child care program is well established in medical literature. Separation from siblings, friends and neighbors emphasizes that child is different from peers. The family declarations highlight this effect of the Army's approach. Specifically, the Shackelford family has 3 children; 2 are included while the 1 with diabetes is excluded. ER 065 at ¶4.

As kids grow up and out of necessary child care, what is needed for care changes. Constant change is what maturity is all about. However, the conditions of the Army's approval process limit flexibility and accommodation for change. Any and all changes require a new request for approval (with a 10-week waiting period before approval). Also, the eligible families who are in or work for the Army put those careers at risk because of the Army's reluctance to properly care for and understand pediatric diabetes.

# F. The Army's conduct deters participation in its child care program.

The deterrent effect of the Army's action and non-action is particularly significant. Many of the family declarations specifically emphasize their reluctance to participate in the Army child care program for many different reasons, including long delay in approval, refusal to provide necessary information and documents, and express unwillingness to help during the application process. ER 040 at ¶120-22; ER 045 at ¶14; ER 053 at ¶126-28; ER 068-069 at ¶23. Clearly, the Army discourages participation. This alone is an adequate basis for factual standing.

These family statements also illustrate the lack of understanding for the acute need for insulin, the safety of insulin administration, and the need for glucose monitoring. In effect, the Army provides too little too late for children with diabetes who need insulin to survive. The Army process is a dangerous facade of accommodation.

#### G. Conclusion

The pediatric diabetes community cares deeply about the well-being of these children and points out that the ADA has the standing, resources, knowledge and commitment to challenge the inadequate and dangerous Army policies, practices and procedures for children with diabetes. For families already saddled with diabetes and difficult financial straits, dealing with the Army is neither effective nor practical. Who could persuasively argue that class actions or hundreds of separate lawsuits would be a better alternative to ADA standing in this case? The question answers itself.

The pediatric diabetes community urges this Court to recognize the standing of the ADA to best represent the interests of children with diabetes in this case. No organization other than the ADA is more suitable for such standing. The involvement of the ADA is absolutely essential to protect the rights of these children to have adequate, safe and timely diabetes care.

Respectfully submitted,

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#### VII. CERTIFICATE OF WORD COUNT

Pursuant to Ninth Circuit Rule 29-2, I certify that this brief complies with the length limits permitted by Federal Rule of appellate Procedure 29(a)(5) and contains 5303 words. The brief's type size and typeface comply with Fed. R. App. P. 32(a)(5) and (6).

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Dated: June 28, 2018

# VIII. ADDENDUM OF EXHIBITS

1.	Children and Adolescents: Standards of Medical Care in Diabetes—2018; 41 DIABETES CARE 5126 (2018)	ADD 1
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# 12. Children and Adolescents: Standards of Medical Care in Diabetes—2018

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American Diabetes Association

The American Diabetes Association (ADA) "Standards of Medical Care in Diabetes" includes ADA's current clinical practice recommendations and is intended to provide the components of diabetes care, general treatment goals and guidelines, and tools to evaluate quality of care. Members of the ADA Professional Practice Committee, a multidisciplinary expert committee, are responsible for updating the Standards of Care annually, or more frequently as warranted. For a detailed description of ADA standards, statements, and reports, as well as the evidence-grading system for ADA's clinical practice recommendations, please refer to the Standards of Care Introduction. Readers who wish to comment on the Standards of Care are invited to do so at professional.diabetes.org/SOC.

#### **TYPE 1 DIABETES**

Three-quarters of all cases of type 1 diabetes are diagnosed in individuals <18 years of age (although recent data using genetic risk scoring would suggest that over 40% of patients with autoimmune diabetes are diagnosed over the age of 30 years) (1). The provider must consider the unique aspects of care and management of children and adolescents with type 1 diabetes, such as changes in insulin sensitivity related to physical growth and sexual maturation, ability to provide self-care, supervision in the child care and school environment, and neurological vulnerability to hypoglycemia and hyperglycemia in young children, as well as possible adverse neurocognitive effects of diabetic ketoacidosis (DKA) (2,3). Attention to family dynamics, developmental stages, and physiological differences related to sexual maturity are all essential in developing and implementing an optimal diabetes treatment plan (4). Due to the nature of clinical research in children, the recommendations for children and adolescents are less likely to be based on clinical trial evidence. However, expert opinion and a review of available and relevant experimental data are summarized in the American Diabetes Association (ADA) position statement "Type 1 Diabetes Through the Life Span" (5) and have been updated in the ADA position statement "Type 1 Diabetes in Children and Adolescents: A Position Statement by the American Diabetes Association" (6).

A multidisciplinary team of specialists trained in pediatric diabetes management and sensitive to the challenges of children and adolescents with type 1 diabetes and their families should provide care for this population. It is essential that diabetes self-management education and support (DSMES), medical nutrition therapy, and psychosocial support be provided at diagnosis and regularly thereafter in a developmentally appropriate format that builds on prior knowledge by individuals experienced with the educational, nutritional, behavioral, and emotional needs of the growing child and family. The appropriate balance between adult supervision and independent self-care should be defined at the first interaction and reevaluated at subsequent visits.

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The balance between adult supervision and independent self-care will evolve as the adolescent gradually becomes an emerging young adult.

# Diabetes Self-management Education and Support

#### Recommendation

 Youth with type 1 diabetes and parents/caregivers (for patients aged <18 years) should receive culturally sensitive and developmentally appropriate individualized diabetes self-management education and support according to national standards at diagnosis and routinely thereafter. B

No matter how sound the medical regimen, it can only be effective if the family and/or affected individuals are able to implement it. Family involvement is a vital component of optimal diabetes management throughout childhood and adolescence. Health care providers (the diabetes care team) who care for children and adolescents must be capable of evaluating the educational, behavioral, emotional, and psychosocial factors that impact implementation of a treatment plan and must work with the individual and family to overcome barriers or redefine goals as appropriate. DSME and DSMS require periodic reassessment, especially as the youth grows, develops, and acquires the need for greater independent self-care skills. In addition, it is necessary to assess the educational needs and skills of day care providers, school nurses, or other school personnel who participate in the care of the young child with diabetes (7).

#### School and Child Care

As a large portion of a child's day is spent in school, close communication with and the cooperation of school or day care personnel are essential for optimal diabetes management, safety, and maximal academic opportunities. Refer to the ADA position statements "Diabetes Care in the School Setting" (8) and "Care of Young Children With Diabetes in the Child Care Setting" (9) for additional details.

#### Psychosocial Issues

#### Recommendations

 At diagnosis and during routine followup care, assess psychosocial issues

- and family stresses that could impact adherence to diabetes management and provide appropriate referrals to trained mental health professionals, preferably experienced in childhood diabetes. E
- Mental health professionals should be considered integral members of the pediatric diabetes multidisciplinary team. E
- Encourage developmentally appropriate family involvement in diabetes management tasks for children and adolescents, recognizing that premature transfer of diabetes care to the child can result in nonadherence and deterioration in glycemic control. A
- Providers should consider asking youth and their parents about social adjustment (peer relationships) and school performance to determine whether further intervention is needed. B
- Assess youth with diabetes for psychosocial and diabetes-related distress, generally starting at 7–8 years of age. B
- At diagnosis and during routine followup care, consider assessing psychosocial issues and family stresses that could impact diabetes management and provide appropriate referrals to trained mental health professionals, preferably experienced in childhood diabetes. E
- Offer adolescents time by themselves with their care provider(s) starting at age 12 years, or when developmentally appropriate. E
- Starting at puberty, preconception counseling should be incorporated into routine diabetes care for all girls of childbearing potential. A

Rapid and dynamic cognitive, developmental, and emotional changes occur during childhood, adolescence, and emerging adulthood. Diabetes management during childhood and adolescence places substantial burdens on the youth and family, necessitating ongoing assessment of psychosocial status and diabetes distress during routine diabetes visits (10–14). Early detection of depression, anxiety, eating disorders, and learning disabilities can facilitate effective treatment options and help minimize adverse effects

on diabetes management and disease outcomes (15). Furthermore, the complexities of diabetes management require ongoing parental involvement in care throughout childhood with developmentally appropriate family teamwork between the growing child/teen and parent in order to maintain adherence and to prevent deterioration in glycemic control (16,17). As diabetes-specific family conflict is related to poorer adherence and glycemic control, it is appropriate to inquire about such conflict during visits and to either help to negotiate a plan for resolution or refer to an appropriate mental health specialist (18). Monitoring of social adjustment (peer relationships) and school performance can facilitate both well-being and academic achievement (19). Suboptimal glycemic control is a risk factor for below average school performance and increased absenteeism (20).

Shared decision-making with youth regarding the adoption of regimen components and self-management behaviors can improve diabetes self-efficacy, adherence, and metabolic outcomes (21). Although cognitive abilities vary, the ethical position often adopted is the "mature minor rule," whereby children after age 12 or 13 years who appear to be "mature" have the right to consent or withhold consent to general medical treatment, except in cases in which refusal would significantly endanger health (22).

Beginning at the onset of puberty or at diagnosis of diabetes, all adolescent girls and women with childbearing potential should receive education about the risks of malformations associated with unplanned pregnancies and poor metabolic control and the use of effective contraception to prevent unplanned pregnancy. Preconception counseling using developmentally appropriate educational tools enables adolescent girls to make wellinformed decisions (23). Preconception counseling resources tailored for adolescents are available at no cost through the ADA (24). Refer to the recent ADA position statement "Psychosocial Care for People With Diabetes" for further details (15).

#### Screening

Screening for psychosocial distress and mental health problems is an important component of ongoing care. It is important to consider the impact of diabetes on quality of life as well as the development of mental health problems related to diabetes distress, fear of hypoglycemia (and hyperglycemia), symptoms of anxiety, disordered eating behaviors as well as eating disorders, and symptoms of depression (25). Consider assessing youth for diabetes distress, generally starting at 7 or 8 years of age (15). Consider screening for depression and disordered eating behaviors using available screening tools (10,26). With respect to disordered eating, it is important to recognize the unique and dangerous disordered eating behavior of insulin omission for weight control in type 1 diabetes (27). The presence of a mental health professional on pediatric multidisciplinary teams highlights the importance of attending to the psychosocial issues of diabetes. These psychosocial factors are significantly related to nonadherence, suboptimal glycemic control, reduced quality of life, and higher rates of acute and chronic di-

#### Glycemic Control

#### Recommendations

abetes complications.

- The majority of children and adolescents with type 1 diabetes should be treated with intensive insulin regimens, either via multiple daily injections or continuous subcutaneous insulin infusion. A
- All children and adolescents with type 1 diabetes should self-monitor blood glucose levels multiple times daily, including premeal, prebedtime, and as needed for safety in specific clinical situations such as exercise, driving, or for symptoms of hypoglycemia. B
- Continuous glucose monitoring should be considered in children and adolescents with type 1 diabetes, whether using injections or continuous subcutaneous insulin infusion, as an additional tool to help

- improve glycemic control. Benefits of continuous glucose monitoring correlate with adherence to ongoing use of the device. **B**
- Automated insulin delivery systems improve glycemic control and reduce hypoglycemia in adolescents and should be considered in adolescents with type 1 diabetes. B
- An A1C goal of <7.5% (58 mmol/mol) is recommended across all pediatric age-groups. E

Current standards for diabetes management reflect the need to lower glucose as safely as possible. This should be done with stepwise goals. When establishing individualized glycemic targets, special consideration should be given to the risk of hypoglycemia in young children (aged <6 years) who are often unable to recognize, articulate, and/or manage hypoglycemia.

Type 1 diabetes can be associated with adverse effects on cognition during childhood and adolescence. Factors that contribute to adverse effects on brain development and function include young age or DKA at onset of type 1 diabetes, severe hypoglycemia at <6 years of age, and chronic hyperglycemia (28,29). However, meticulous use of new therapeutic modalities, such as rapid- and long-acting insulin analogs, technological advances (e.g., continuous glucose monitors, lowglucose suspend insulin pumps, and automated insulin delivery systems), and intensive self-management education now make it more feasible to achieve excellent glycemic control while reducing the incidence of severe hypoglycemia (30-39). A strong relationship exists between frequency of blood glucose monitoring and glycemic control (32-41).

The Diabetes Control and Complications Trial (DCCT), which did not enroll children <13 years of age, demonstrated

that near normalization of blood glucose levels was more difficult to achieve in adolescents than in adults. Nevertheless, the increased use of basal-bolus regimens, insulin pumps, frequent blood glucose monitoring, goal setting, and improved patient education in youth from infancy through adolescence have been associated with more children reaching the blood glucose targets recommended by ADA (42-45), particularly in those families in which both the parents and the child with diabetes participate jointly to perform the required diabetes-related tasks. Furthermore, studies documenting neurocognitive imaging differences related to hyperglycemia in children provide another motivation for lowering glycemic targets (2).

In selecting glycemic goals, the longterm health benefits of achieving a lower A1C should be balanced against the risks of hypoglycemia and the developmental burdens of intensive regimens in children and youth. In addition, achieving lower A1C levels is more likely to be related to setting lower A1C targets (46,47). A1C and blood glucose goals are presented in **Table 12.1**.

#### **Autoimmune Conditions**

#### Recommendation

 Assess for the presence of autoimmune conditions associated with type 1 diabetes soon after the diagnosis and if symptoms develop. B

Because of the increased frequency of other autoimmune diseases in type 1 diabetes, screening for thyroid dysfunction and celiac disease should be considered (48,49). Periodic screening in asymptomatic individuals has been recommended, but the optimal frequency and benefit of screening are unclear.

Although much less common than thyroid dysfunction and celiac disease, other autoimmune conditions, such as Addison

Table 12.1-Blood glucose and A1C goals for children and adolescents with type 1 diabetes

Blood glucose goal range

		_	
Before meals	Bedtime/overnight	A1C	Rationale
90–130 mg/dL (5.0–7.2 mmol/L)	90–150 mg/dL (5.0–8.3 mmol/L)	<7.5% (58 mmol/mol)	A lower goal (<7.0% [53 mmol/mol]) is reasonable if it can be achieved without excessive hypoglycemia

#### Key concepts in setting glycemic goals:

- Goals should be individualized, and lower goals may be reasonable based on a benefit-risk assessment.
- Blood glucose goals should be modified in children with frequent hypoglycemia or hypoglycemia unawareness.
- Postprandial blood glucose values should be measured when there is a discrepancy between preprandial blood glucose values and A1C levels and to assess preprandial insulin doses in those on basal-bolus or pump regimens.

disease (primary adrenal insufficiency), autoimmune hepatitis, autoimmune gastritis, dermatomyositis, and myasthenia gravis, occur more commonly in the population with type 1 diabetes than in the general pediatric population and should be assessed and monitored as clinically indicated.

#### Thyroid Disease

#### Recommendations

- Consider testing individuals with type 1 diabetes for antithyroid peroxidase and antithyroglobulin antibodies soon after the diagnosis.
- Measure thyroid-stimulating hormone concentrations at diagnosis when clinically stable or soon after glycemic control has been established. If normal, consider rechecking every 1–2 years or sooner if the patient develops symptoms suggestive of thyroid dysfunction, thyromegaly, an abnormal growth rate, or an unexplained glycemic variation. A

Autoimmune thyroid disease is the most common autoimmune disorder associated with diabetes, occurring in 17-30% of patients with type 1 diabetes (50). At the time of diagnosis, about 25% of children with type 1 diabetes have thyroid autoantibodies (51); their presence is predictive of thyroid dysfunction most commonly hypothyroidism, although hyperthyroidism occurs in  $\sim$ 0.5% of patients with type 1 diabetes (52, 53). For thyroid autoantibodies, a recent study from Sweden indicated antithyroid peroxidase antibodies were more predictive than antithyroglobulin antibodies in multivariate analysis (54). Thyroid function tests may be misleading (euthyroid sick syndrome) if performed at the time of diagnosis owing to the effect of previous hyperglycemia, ketosis or ketoacidosis, weight loss, etc. Therefore, if performed at diagnosis and slightly abnormal, thyroid function tests should be performed soon after a period of metabolic stability and good glycemic control. Subclinical hypothyroidism may be associated with increased risk of symptomatic hypoglycemia (55) and reduced linear growth rate. Hyperthyroidism alters glucose metabolism and usually causes deterioration of glycemic control.

#### Celiac Disease

#### Recommendations

- Screen individuals with type 1 diabetes for celiac disease soon after
  the diagnosis of diabetes by measuring IgA tissue transglutaminase
  antibodies, with documentation of
  normal total serum IgA levels or, if
  IgA deficient, IgG tissue transglutamine and deamidated gliadin antibodies. B
- Repeat screening within 2 years of diabetes diagnosis and then again after 5 years and consider more frequent screening in children who have symptoms or a first-degree relative with celiac disease. B
- Individuals with biopsy-confirmed celiac disease should be placed on a gluten-free diet and have a consultation with a dietitian experienced in managing both diabetes and celiac disease. B

Celiac disease is an immune-mediated disorder that occurs with increased frequency in patients with type 1 diabetes (1.6–16.4% of individuals compared with 0.3–1% in the general population) (48,49, 56–58,59).

Screening. Screening for celiac disease includes measuring serum levels of IgA and tissue transglutaminase antibodies, or, with IgA deficiency, screening can include measuring IgG tissue transglutaminase antibodies or IgG deamidated gliadin peptide antibodies. Because most cases of celiac disease are diagnosed within the first 5 years after the diagnosis of type 1 diabetes, screening should be considered at the time of diagnosis and repeated at 2 and then 5 years (58).

Although celiac disease can be diagnosed more than 10 years after diabetes diagnosis, there are insufficient data after 5 years to determine the optimal screening frequency. Measurement of tissue transglutaminase antibody should be considered at other times in patients with symptoms suggestive of celiac disease (58). A small-bowel biopsy in antibodypositive children is recommended to confirm the diagnosis (60). European guidelines on screening for celiac disease in children (not specific to children with type 1 diabetes) suggest that biopsy may not be necessary in symptomatic children with high antibody titers (i.e., greater than 10 times the upper limit of normal)

provided that further testing is performed (verification of endomysial antibody positivity on a separate blood sample). It is also advisable to check for HLA types in patients who are diagnosed without a small intestinal biopsy. Asymptomatic at-risk children should have an intestinal biopsy (61).

In symptomatic children with type 1 diabetes and confirmed celiac disease, glutenfree diets reduce symptoms and rates of hypoglycemia (62). The challenging dietary restrictions associated with having both type 1 diabetes and celiac disease place a significant burden on individuals. Therefore, a biopsy to confirm the diagnosis of celiac disease is recommended, especially in asymptomatic children, before endorsing significant dietary changes. A gluten-free diet was beneficial in asymptomatic adults with positive antibodies confirmed by biopsy (63).

# Management of Cardiovascular Risk Factors

Hypertension

#### Recommendations

#### Screening

Blood pressure should be measured at each routine visit. Children found to have high-normal blood pressure (systolic blood pressure or diastolic blood pressure ≥90th percentile for age, sex, and height) or hypertension (systolic blood pressure or diastolic blood pressure ≥95th percentile for age, sex, and height) should have elevated blood pressure confirmed on 3 separate days. B

#### **Treatment**

- Initial treatment of high-normal blood pressure (systolic blood pressure consistently ≥90th percentile for age, sex, and height) includes dietary modification and increased exercise, if appropriate, aimed at weight control. If target blood pressure is not reached within 3–6 months of initiating lifestyle intervention, pharmacologic treatment should be considered. E
- In addition to lifestyle modification, pharmacologic treatment of hypertension (systolic blood pressure or diastolic blood pressure consistently ≥95th percentile for age, sex, and height) should be considered as

- ACE inhibitors or angiotensin receptor blockers may be considered for the treatment of elevated (>30 mg/g) urinary albumin-to-creatinine ratio (B) and hypertension (E) in children and adolescents, following reproductive counseling and implementation of effective birth control due to the potential teratogenic effects of both drug classes. E
- The goal of treatment is blood pressure consistently <90th percentile for age, sex, and height. E</li>

Blood pressure measurements should be performed using the appropriate size cuff with the child seated and relaxed. Hypertension should be confirmed on at least 3 separate days. Evaluation should proceed as clinically indicated. Treatment is generally initiated with an ACE inhibitor, but an angiotensin receptor blocker can be used if the ACE inhibitor is not tolerated (e.g., due to cough) (64).

Normal blood pressure levels for age, sex, and height and appropriate methods for measurement are available online at nhlbi.nih.gov/files/docs/resources/heart/hbp\_ped.pdf.

#### Dyslipidemia

#### Recommendations

#### **Testing**

- Obtain a lipid profile in children
  ≥10 years of age soon after the diagnosis of diabetes (after glucose control has been established). If abnormal, repeat lipid profile after fasting. E
- If lipids are abnormal, annual monitoring is reasonable. If LDL cholesterol values are within the accepted risk level (<100 mg/dL [2.6 mmol/L]), a lipid profile repeated every 5 years is reasonable. E</li>

#### Treatment

- Initial therapy should consist of optimizing glucose control and medical nutrition therapy using a Step
   American Heart Association diet to decrease the amount of saturated fat in the diet. B
- After the age of 10 years, addition of a statin is suggested in patients who, despite medical nutrition therapy and lifestyle changes, continue to have LDL cholesterol >160

mg/dL (4.1 mmol/L) or LDL cholesterol >130 mg/dL (3.4 mmol/L) and one or more cardiovascular disease risk factors, following reproductive counseling and implementation of effective birth control due to the potential teratogenic effects of statins. B

The goal of therapy is an LDL cholesterol value <100 mg/dL (2.6 mmol/L). E</li>

Population-based studies estimate that 14–45% of children with type 1 diabetes have two or more atherosclerotic cardio-vascular disease (ASCVD) risk factors (65–67), and the prevalence of CVD risk factors increases with age (67), with girls having a higher risk burden than boys (66).

Pathophysiology. The atherosclerotic process begins in childhood, and although ASCVD events are not expected to occur during childhood, observations using a variety of methodologies show that youth with type 1 diabetes may have subclinical CVD within the first decade of diagnosis (68–70). Studies of carotid intima-media thickness have yielded inconsistent results (64).

Treatment. Pediatric lipid guidelines provide some guidance relevant to children with type 1 diabetes (71–73); however, there are few studies on modifying lipid levels in children with type 1 diabetes. A 6-month trial of dietary counseling produced a significant improvement in lipid levels (74); likewise, a lifestyle intervention trial with 6 months of exercise in adolescents demonstrated improvement in lipid levels (75).

Although intervention data are sparse, the American Heart Association categorizes children with type 1 diabetes in the highest tier for cardiovascular risk and recommends both lifestyle and pharmacologic treatment for those with elevated LDL cholesterol levels (73,76). Initial therapy should be with a Step 2 American Heart Association diet, which restricts saturated fat to 7% of total calories and restricts dietary cholesterol to 200 mg/day. Data from randomized clinical trials in children as young as 7 months of age indicate that this diet is safe and does not interfere with normal growth and development (77).

For children with a significant family history of CVD, the National Heart, Lung,

and Blood Institute recommends obtaining a fasting lipid panel beginning at 2 years of age (71). Abnormal results from a random lipid panel should be confirmed with a fasting lipid panel. Data from the SEARCH for Diabetes in Youth (SEARCH) study show that improved glucose control over a 2-year period is associated with a more favorable lipid profile; however, improved glycemic control alone will not normalize lipids in youth with type 1 diabetes and dyslipidemia (78).

Neither long-term safety nor cardiovascular outcome efficacy of statin therapy has been established for children; however, studies have shown shortterm safety equivalent to that seen in adults and efficacy in lowering LDL cholesterol levels in familial hypercholesterolemia or severe hyperlipidemia, improving endothelial function and causing regression of carotid intimal thickening (79,80). Statins are not approved for patients aged <10 years, and statin treatment should generally not be used in children with type 1 diabetes before this age. Statins are contraindicated in pregnancy; therefore, prevention of unplanned pregnancies is of paramount importance for postpubertal girls (see Section 13 "Management of Diabetes in Pregnancy" for more information). The multicenter, randomized, placebo-controlled Adolescent Type 1 Diabetes Cardio-Renal Intervention Trial (AdDIT) provides safety data on pharmacologic treatment with an ACE inhibitor and statin in adolescents with type 1 diabetes.

#### Smoking

#### Recommendation

 Elicit a smoking history at initial and follow-up diabetes visits; discourage smoking in youth who do not smoke, and encourage smoking cessation in those who do smoke. A

The adverse health effects of smoking are well recognized with respect to future cancer and CVD risk. Despite this, smoking rates are significantly higher among youth with diabetes than among youth without diabetes (81,82). In youth with diabetes, it is important to avoid additional CVD risk factors. Smoking increases the risk of onset of albuminuria; therefore, smoking avoidance is important to prevent both microvascular and macrovascular complications (71,83). Discouraging cigarette smoking, including e-cigarettes,

is an important part of routine diabetes care. In younger children, it is important to assess exposure to cigarette smoke in the home due to the adverse effects of secondhand smoke and to discourage youth from ever smoking if exposed to smokers in childhood.

# Microvascular Complications Diabetic Kidney Disease

#### Recommendations

#### Screening

 Annual screening for albuminuria with a random spot urine sample for albumin-to-creatinine ratio should be performed at puberty or at age ≥10 years, whichever is earlier, once the child has had diabetes for 5 years. B

#### **Treatment**

When persistently elevated urinary albumin-to-creatinine ratio (>30 mg/g) is documented with at least two of three urine samples, treatment with an ACE inhibitor or angiotensin receptor blocker may be considered and the dose titrated to maintain blood pressure within the age-appropriate normal range. The urine samples should be obtained over a 6-month interval following efforts to improve glycemic control and normalize blood pressure. B

Data from 7,549 participants <20 years of age in the T1D Exchange clinic registry emphasize the importance of good glycemic and blood pressure control, particularly as diabetes duration increases, in order to reduce the risk of diabetic kidney disease. The data also underscore the importance of routine screening to ensure early diagnosis and timely treatment of albuminuria (84). An estimation of glomerular filtration rate (GFR), calculated using GFR estimating equations from the serum creatinine, height, age, and sex (85), should be considered at baseline and repeated as indicated based on clinical status, age, diabetes duration, and therapies. Improved methods are needed to screen for early GFR loss, since estimated GFR is inaccurate at GFR >60 ml/min/1.73 m<sup>2</sup> (85,86). The AdDIT study in adolescents with type 1 diabetes demonstrated safety of ACE inhibitor treatment, but did not change the urinary albumin-to-creatinine ratio over the course of the study (87).

#### Retinopathy

#### Recommendations

- An initial dilated and comprehensive eye examination is recommended once youth have had type 1 diabetes for 3–5 years, provided they are age ≥10 years or puberty has started, whichever is earlier.
- After the initial examination, annual routine follow-up is generally recommended. Less-frequent examinations, every 2 years, may be acceptable on the advice of an eye care professional and based on risk factor assessment. E

Retinopathy (like albuminuria) most commonly occurs after the onset of puberty and after 5–10 years of diabetes duration (88). Referrals should be made to eye care professionals with expertise in diabetic retinopathy and experience in counseling the pediatric patient and family on the importance of early prevention and intervention.

#### Neuropathy

#### Recommendation

 Consider an annual comprehensive foot exam at the start of puberty or at age ≥10 years, whichever is earlier, once the youth has had type 1 diabetes for 5 years. B

Diabetic neuropathy rarely occurs in prepubertal children or after only 1-2 years of diabetes (88), although data suggest a prevalence of distal peripheral neuropathy of 7% in 1,734 youth with type 1 diabetes and associated with the presence of CVD risk factors (89). A comprehensive foot exam, including inspection, palpation of dorsalis pedis and posterior tibial pulses, and determination of proprioception, vibration, and monofilament sensation, should be performed annually along with an assessment of symptoms of neuropathic pain (90). Foot inspection can be performed at each visit to educate youth regarding the importance of foot care (see Section 10 "Microvascular Complications and Foot Care").

#### **TYPE 2 DIABETES**

For information on testing for type 2 diabetes and prediabetes in children and adolescents, please refer to Section 2 "Classification and Diagnosis of Diabetes." For additional support for these recommendations, see the ADA position statement "Evaluation and Management of Youth-Onset Type 2 Diabetes (91).

Type 2 diabetes in youth has increased over the past 20 years, and recent estimates suggest an incidence of  $\sim$ 5,000 new cases per year in the U.S. (92). The Centers for Disease Control and Prevention published projections for type 2 diabetes prevalence using the SEARCH database—assuming a 2.3% annual increase, the prevalence in those under 20 years of age will quadruple in 40 years (93,94).

Evidence suggests that type 2 diabetes in youth is different not only from type 1 diabetes but also from type 2 diabetes in adults and has unique features, such as a more rapidly progressive decline in β-cell function and accelerated development of diabetes complications (95,96). Type 2 diabetes disproportionately impacts youth of ethnic and racial minorities and can occur in complex psychosocial and cultural environments, which may make it difficult to sustain healthy lifestyle changes and self-management behaviors. Additional risk factors associated with type 2 diabetes in youth include adiposity, family history of diabetes, female sex, and low socioeconomic status (96).

As with type 1 diabetes, youth with type 2 diabetes spend much of the day in school. Therefore, close communication with and the cooperation of school personnel are essential for optimal diabetes management, safety, and maximal academic opportunities.

#### Recommendations

#### Screening and Diagnosis

- Risk-based screening for prediabetes and/or type 2 diabetes should be considered in children and adolescents after the onset of puberty or ≥10 years of age, whichever occurs earlier, who are overweight (BMI >85th %) or obese (BMI >95th %) and who have one or more additional risk factors for diabetes (see Table 2.5). A
- If tests are normal, repeat testing at a minimum of 3-year intervals E, or more frequently if BMI is increasing. C
- Fasting plasma glucose, 2-h plasma glucose during a 75-g oral glucose tolerance test, and A1C can be used

to test for prediabetes or diabetes in children and adolescents. B

In the last decade, the incidence and prevalence of type 2 diabetes in adolescents has increased dramatically, especially in racial and ethnic minority populations (97). A few recent studies suggest oral glucose tolerance tests or fasting plasma glucose values as more suitable diagnostic tests than A1C in the pediatric population, especially among certain ethnicities (98). However, many of these studies do not recognize that diabetes diagnostic criteria are based on long-term health outcomes, and validations are not currently available in the pediatric population (99). ADA acknowledges the limited data supporting A1C for diagnosing type 2 diabetes in children and adolescents. Although A1C is not recommended for diagnosis of diabetes in children with cystic fibrosis or symptoms suggestive of acute onset of type 1 diabetes and only A1C assays without interference are appropriate for children with hemoglobinopathies, ADA continues to recommend A1C for diagnosis of type 2 diabetes in this population (100,101).

#### Diagnostic Challenges

Given the current obesity epidemic, distinguishing between type 1 and type 2 diabetes in children can be difficult. Overweight and obesity are common in children with type 1 diabetes (102), and diabetesassociated autoantibodies and ketosis may be present in pediatric patients with features of type 2 diabetes (including obesity and acanthosis nigricans) (103). At onset, DKA occurs in  $\sim$ 6% of youth aged 10-19 years with type 2 diabetes (104). Accurate diagnosis is critical, as treatment regimens, educational approaches, dietary advice, and outcomes differ markedly between patients with the two diagnoses.

#### Management

#### Recommendations

#### Lifestyle Management

 Overweight or obese youth with type 2 diabetes and their families should be provided with developmentally and culturally appropriate comprehensive lifestyle programs that are integrated with diabetes management to achieve 7-10% decrease in excess weight. C

- Given the necessity of long-term weight management for children and adolescents with type 2 diabetes, lifestyle intervention should be based on a chronic care model and offered in the context of diabetes care. E
- Youth with diabetes, like all children, should be encouraged to participate in at least 60 min of moderate to vigorous physical activity per day (and strength training on at least 3 days/week) B and to decrease sedentary behavior. C
- Nutrition for youth with type 2 diabetes, like all children, should focus on healthy eating patterns that emphasize consumption of nutrientdense, high-quality foods and decreased consumption of caloriedense, nutrient-poor foods, particularly sugar-added beverages. B

#### Pharmacologic Management

- Initiate pharmacologic therapy, in addition to lifestyle therapy, at diagnosis of type 2 diabetes. A
- In metabolically stable patients (A1C <8.5% and asymptomatic), metformin is the initial pharmacologic treatment of choice if renal function is >30 ml/min/1.73 m<sup>2</sup>. A
- Youth with marked hyperglycemia (blood glucose ≥250 mg/dL [13.9 mmol/L], A1C≥8.5% [69 mmol/mol]) without ketoacidosis at diagnosis who are symptomatic with polyuria, polydipsia, nocturia, and/or weight loss should be treated initially with basal insulin while metformin is initiated and titrated to maximally tolerated dose to achieve A1C goal. E
- When the A1C target is no longer met with metformin monotherapy, or if contraindications or intolerable side effects of metformin develop, basal insulin therapy should be initiated. E
- In patients initially treated with basal insulin and metformin who are meeting glucose targets based on home blood glucose monitoring, basal insulin can be tapered over 2-6 weeks by decreasing the insulin dose by 10-30% every few days. A
- Use of medications not approved by the U.S. Food and Drug Administration for youth with type 2 diabetes is not recommended outside of research trials. B

 All youth with type 2 diabetes and their families should receive comprehensive diabetes self-management education and support that is specific to youth with type 2 diabetes and culturally competent. B

The general treatment goals for youth with type 2 diabetes are the same as those for youth with type 1 diabetes. A multidisciplinary diabetes team, including a physician, diabetes nurse educator, registered dietitian, and psychologist or social worker, is essential. In addition to blood glucose control, initial treatment must include management of comorbidities such as obesity, dyslipidemia, hypertension, and microvascular complications.

Current treatment options for youthonset type 2 diabetes are limited to two approved drugs—insulin and metformin (95). Presentation with ketosis or ketoacidosis requires a period of insulin therapy until fasting and postprandial glycemia have been restored to normal or near-normal levels. Metformin therapy may be used as an adjunct after resolution of ketosis/ketoacidosis. Initial treatment should also be with insulin when the distinction between type 1 diabetes and type 2 diabetes is unclear and in patients who have random blood glucose concentrations 250 mg/dL (13.9 mmol/L) and/or A1C ≥8.5% (69 mmol/mol) (105).

Patients and their families must prioritize lifestyle modifications such as eating a balanced diet, achieving and maintaining a healthy weight, and exercising regularly. A family-centered approach to nutrition and lifestyle modification is essential in children with type 2 diabetes, and nutrition recommendations should be culturally appropriate and sensitive to family resources (see Section 4 "Lifestyle Management"). Given the complex social and environmental context surrounding youth with type 2 diabetes, individual-level lifestyle interventions may not be sufficient to target the complex interplay of family dynamics, mental health, community readiness, and the broader environmental system (95).

When insulin treatment is not required, initiation of metformin is recommended. The Treatment Options for Type 2 Diabetes in Adolescents and Youth (TODAY) study found that metformin alone provided durable glycemic control (A1C ≤8% [64 mmol/mol] for 6 months) in approximately half of the subjects (106). To date, the TODAY study is the only trial combining lifestyle and metformin therapy in youth with type 2 diabetes; the combination did not perform better than metformin alone in achieving durable glycemic control (106).

Small retrospective analyses and a recent prospective multicenter nonrandomized study suggest that bariatric or metabolic surgery may have similar benefits in obese adolescents with type 2 diabetes compared with those observed in adults. Teenagers experience similar degrees of weight loss, diabetes remission, and improvement of cardiometabolic risk factors for at least 3 years after surgery (107). No randomized trials, however, have yet compared the effectiveness and safety of surgery to those of conventional treatment options in adolescents (108).

#### Comorbidities

Comorbidities may already be present at the time of diagnosis of type 2 diabetes in youth (96,109). Therefore, blood pressure measurement, a fasting lipid panel, assessment of random urine albumin-tocreatinine ratio, and a dilated eye examination should be performed at diagnosis. Thereafter, screening guidelines and treatment recommendations for hypertension, dyslipidemia, urine albumin excretion, and retinopathy are similar to those for youth with type 1 diabetes. Additional problems that may need to be addressed include polycystic ovary disease and other comorbidities associated with pediatric obesity, such as sleep apnea, hepatic steatosis, orthopedic complications, and psychosocial concerns. The ADA consensus report "Youth-Onset Type 2 Diabetes Consensus Report: Current Status, Challenges, and Priorities" (95) and an American Academy of Pediatrics clinical practice guideline (110) provide guidance on the prevention, screening, and treatment of type 2 diabetes and its comorbidities in children and adolescents.

# TRANSITION FROM PEDIATRIC TO ADULT CARE

#### Recommendations

- Pediatric diabetes providers and families should begin to prepare youth for transition in early adolescence and, at the latest, at least 1 year before the transition to adult health care. E
- Both pediatric and adult diabetes care providers should provide sup-

port and links to resources for transitioning young adults. **B** 

Care and close supervision of diabetes management are increasingly shifted from parents and other adults to the youth with type 1 or type 2 diabetes throughout childhood and adolescence. The shift from pediatric to adult health care providers, however, often occurs abruptly as the older teen enters the next developmental stage referred to as emerging adulthood (111), which is a critical period for young people who have diabetes. During this period of major life transitions, youth begin to move out of their parents' homes and must become fully responsible for their diabetes care. Their new responsibilities include self-management of their diabetes, making medical appointments, and financing health care, once they are no longer covered by their parents' health insurance plans (ongoing coverage until age 26 years is currently available under provisions of the U.S. Affordable Care Act). In addition to lapses in health care, this is also a period associated with deterioration in glycemic control; increased occurrence of acute complications; psychosocial, emotional, and behavioral challenges; and the emergence of chronic complications (112–115). The transition period from pediatric to adult care is prone to fragmentation in health care delivery, which may adversely impact health care quality, cost, and outcomes (116).

Although scientific evidence is limited, it is clear that comprehensive and coordinated planning that begins in early adolescence, or at least 1 year before the date of transition, is necessary to facilitate a seamless transition from pediatric to adult health care (112,113,117–119). A comprehensive discussion regarding the challenges faced during this period, including specific recommendations, is found in the ADA position statement "Diabetes Care for Emerging Adults: Recommendations for Transition From Pediatric to Adult Diabetes Care Systems" (113).

The Endocrine Society in collaboration with the ADA and other organizations has developed transition tools for clinicians and youth and families (118).

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# Care of Young Children With Diabetes in the Child Care Setting: A Position Statement of the American Diabetes Association

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Diabetes is a relatively common chronic disease of childhood (1); however, capturing prevalence data in children with type 1 and type 2 diabetes has been challenging. The comprehensive SEARCH for Diabetes in Youth (SEARCH) study has made significant strides in better understanding disease prevalence in the pediatric population. A recent SEARCH study found that 1.93 per 1,000 youth (aged <20 years) were diagnosed with type 1 diabetes (2), an increase of 21.1% from 2001 to 2009, with increases seen in all ethnic groups but with non-Hispanic whites disproportionately affected (3). For type 2 diabetes, the SEARCH study reported a prevalence of 0.46 per 1,000 youth (aged 10–20 years), an increase of 30.5% from 2001 to 2009 in all ethnicities (3). As youth rarely die of diabetes, the increase in prevalence is most likely attributed to increased incidence.

An annual increase of 2.3% in type 1 diabetes incidence has been reported in children, with children aged <5 years experiencing the greatest increase relative to all children (4). As type 2 diabetes is rarely seen in children younger than 10 years of age (3), this Position Statement will primarily focus on type 1 diabetes. The primary objective of this Position Statement is to explain that young children (aged ≤5 years) are a vulnerable population and have unique diabetes management needs. Our goal is to describe the diabetes management recommendations in the child care setting. The child care setting includes day care, camp, and other programs where young children with diabetes are enrolled. This Position Statement is meant to guide child care providers in caring for young children with diabetes and is not intended to provide specific advice on the medical management for this population. While Position Statements contain evidence-based recommendations, all of the information that pertains to young children is expert opinion only. For more detailed information on the medical management of type 1 diabetes in children, please refer to the American Diabetes Association's (ADA's) "Standards of Medical Care in Diabetes — 2014" (5) and "Type 1 Diabetes Through the Life Span: A Position Statement of the American Diabetes Association" (6).

#### UNIQUE CHALLENGES FOR THE YOUNG CHILD

Infants, toddlers, and preschool-age children (≤5 years of age) are enrolled in the more than 330,000 child care programs across the country (7). These children wholly depend on adults for most, if not all, aspects of their care. Pediatric health care providers, parents/guardians, and child care staff must work together to ensure that young children with diabetes are provided with the safest possible child care environment. This collaboration is essential to achieve a seamless transition in care from home to the child care setting.

Managing type 1 diabetes in young children in child care programs presents unique challenges due to the young child's developmental level. The limited communication and motor skills, cognitive abilities, and emotional maturity of young children can challenge even the most experienced child care provider. For example, young children with hypo- or hyperglycemia may or may not exhibit abnormal behavior or irritability. As erratic behavior is typical in this age-group, the child care provider may not recognize hypo- or hyperglycemic symptoms and may miss

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the fact that the behavior is caused by low or high blood glucose levels that may require treatment.

The diabetes regimen must be adapted quickly to the child's dynamic growth and development. As the child develops and desires greater autonomy, child care providers and parents/guardians may face challenges with the toddler's refusal to cooperate with his or her diabetes care regimen (8). Once the child enters the prekindergarten years, he or she may begin to be able to participate in his or her own care by indicating food preferences, checking blood glucose, and choosing a finger-prick or injection site. With further cognitive and physical development, he or she may verbalize symptoms and become more cooperative, but the child still needs constant supervision and blood glucose monitoring to detect hypo- or hyperglycemia. The age at which children are able to perform self-care tasks is variable and depends on the individual child's capabilities, but self-care is not expected from the young child and the parent/guardian or other caregiver must provide diabetes management and perform associated diabetes care tasks such as blood glucose monitoring and insulin administration (5,8) (Table 1).

Language barriers, ethnic and cultural practices, limited resources and support, geography (rural vs. urban setting), and health literacy and capabilities must also be considered in developing the care plan.

Another challenge in the child care setting may be staff turnover and ensuring that trained staff members remain available. Regardless, the child care program must be prepared to provide needed care to the child, and parents and health care providers play a pivotal role in partnering with the child care staff.

#### **Key Points**

- The safety, health, and well-being of the child as he or she transitions from home to the child care setting are achieved through effective collaboration between the diabetes health care provider, parents/guardians, and child care staff.
- Adults must provide most, if not all, of the diabetes care to young children because of their limited motor, cognitive, and communication skills as well as

other abilities that are necessary to participate in self-management.

- As the child grows older and becomes closer to school age, he or she may participate in care tasks as appropriate for the individual child, but adult supervision must always be present.
- Challenges in the child care setting include staff turnover, language barriers, ethnic and cultural practices, limited resources and support, geography (rural vs. urban setting), and health literacy and capabilities.

#### **DIABETES CARE**

The Diabetes Control and Complications Trial (DCCT) showed a significant link between blood glucose control and a slower onset and progression of diabetes complications in adults and adolescents, with improved glycemic control decreasing the risk of micro- and macrovascular complications (5,9,10). Although the DCCT did not include young children (the lower age limit at enrollment was 13 years), the general message optimize blood glucose control while avoiding hypoglycemia—has been clinically applied to young children. Furthermore, recent data from cross-sectional neuroimaging studies in young children appear to reinforce the importance of aiming for blood glucose levels in range and avoiding hypo- and hyperglycemia (11).

#### **Nutrition and Physical Activities**

The parent/guardian remains primarily responsible for determining and providing healthy food choices for the child. The parent/guardian should educate the staff on general information on the carbohydrate content of the food, regardless of whether it is provided by the parent/guardian or child care program. If a child care program provides the meals and snacks, the parent/guardian and the child care provider should work together to determine appropriate food choices and portion sizes for the child. The child care program should ensure that the child eats the appropriate amount of food that is being covered by insulin in accordance with the diabetes medical management plan (DMMP). See the section on DMMP for further details.

For children who regularly attend child care programs for longer durations or where meals or snacks and physical activity are part of the daily schedule, sufficient staff should receive comprehensive training in diabetes management and be prepared to provide diabetes care as needed. At least one staff member should be available at all times to help with food decisions, blood glucose monitoring, and insulin administration.

Increased sensitivity in caring for the child around special occasions (such as parties/celebrations), physical activities, or illnesses is particularly important. The child should be allowed to participate in celebrations, but special considerations may be required to accommodate the child's diabetes needs. Effective communication between the child care staff and the parent/guardian to anticipate the adjustments (e.g., administering additional insulin to account for the birthday cake) will enable the young child to feel included. Resources are available to parents/guardians, child care providers, and health care providers to assist with this education and training (12-15).

Children who participate in programs for only a few hours may consume snacks and not meals; therefore, insulin administration may not be required in the child's DMMP. However, at a minimum, in order to facilitate safe diabetes care in all child care programs, child care staff must have a basic understanding of diabetes; be able to check blood glucose levels; be able to prevent, recognize, and treat hypoglycemia; be able to handle diabetes emergencies; and know who to contact for help (12–14,16).

#### Hypoglycemia

For the very young child, the diabetes management priority is the prevention and management of hypoglycemia and the avoidance of wide fluctuations in blood glucose levels. Parents/guardians face the perpetual struggle of balancing the risk of long-term complications from hyperglycemia with the fear of acute hypoglycemia, all while trying to facilitate a "normal" childhood. More notably, parents worry about the possibility of cognitive deficits and/or death if a severe hypoglycemic event is undetected and untreated. Therefore, hypoglycemia prevention is critical. Child care staff should be educated on how to prevent and recognize hypoglycemia by monitoring the child's food consumption, activity, and behavior and confirming a suspected low with blood glucose monitoring (5,8,17). Parents/guardians should provide specific

Developmental stages (ages)	Normal developmental tasks	Type 1 diabetes management priorities	Family issues in type 1 diabetes management
Infancy (0–12 months)	Developing a trusting relationship or bond with primary caregiver(s)	Preventing and treating hypoglycemia Avoiding extreme fluctuations in blood glucose levels	Coping with stress Sharing the burden of care to avoid parent burnout
Toddler (13–26 months)	Developing a sense of mastery and autonomy	Preventing hypoglycemia Avoiding extreme fluctuations in blood glucose levels due to irregular food intake	Establishing a schedule Managing the picky eater Limit-setting and coping with toddler's lack of cooperation with regimen Sharing the burden of care
Preschooler and early elementary school (3–7 years)	Developing initiative in activities and confidence in self	Preventing hypoglycemia Coping with unpredictable appetite and activity Positively reinforcing cooperation with regimen Trusting other caregivers with diabetes management	Reassuring the child that diabetes is no one's fault Educating other caregivers about diabetes management
Older elementary school (8–11 years)	Developing skills in athletic, cognitive, artistic, and social areas Consolidating self-esteem with respect to the peer group	Making diabetes regimen flexible to allow for participation in school or peer activities Child learning short- and long-term benefits of optimal control	Maintaining parental involvement in insulin and blood glucose management tasks while allowing for independent self-care for special occasions  Continuing to educate school and other caregivers
Early adolescence (12–15 years)	Managing body changes Developing a strong sense of self-identity	Increasing insulin requirements during puberty Diabetes management and blood glucose control becoming more difficult Weight and body image concerns	Renegotiating parent and teenager's roles in diabetes management to be acceptable to both Learning coping skills to enhance ability to self-manage Preventing and intervening in diabetes-related family conflict Monitoring for signs of depression, eating disorders, and risky behaviors
Later adolescence (16–19 years)	Establishing a sense of identity after high school (decisions about location, social issues, work, and education)	Starting an ongoing discussion of transition to a new diabetes team (discussion may begin in earlier adolescent years) Integrating diabetes into new lifestyle	Supporting the transition to independence Learning coping skills to enhance ability to self-manage Preventing and intervening with diabetes-related family conflict Monitoring for signs of depression, eating disorders, and risky behaviors

strategies, if needed, to help the child care staff address the individual child's specific needs. Routine blood glucose monitoring at prespecified times may help to detect hypoglycemia before it manifests with acute symptoms in the child.

#### Hyperglycemia

Although hypoglycemia is a significant concern, hyperglycemia should be managed as well. The child may experience frequent urination (polyuria), which may be confused with "heavy diapers" or "wetting accidents," a common occurrence in this age-group anyway. A child care provider unfamiliar with diabetes and polyuria may not realize that the child is hyperglycemic, requiring insulin, and instead may feed the child or give him or her juice, inadvertently aggravating hyperglycemia. Untreated hyperglycemia may lead to ketone production, which may be measured by checking urine ketones.

The ADA has previously recommended higher blood glucose targets for young children in an effort to prevent hypoglycemia. However, the ADA has recently adjusted its target recommendations to an A1C of <7.5% in all pediatric age-groups (<19 years of age) but with the goal of achieving the best A1C possible without hypoglycemia. The new recommendation is a product of reduced hypoglycemia seen with newer rapid-acting insulin

analogs and improved glucose monitoring devices and the awareness of the potential impact of chronic hyperglycemia on the development of future longterm complications (6).

#### **Blood Glucose Monitoring**

Blood glucose monitoring allows child care providers to assess if a child is hypo- or hyperglycemic and perform appropriate interventions. Blood glucose levels need to be checked before meals/snacks, before physical activity, and when the child exhibits symptoms of hypo- or hyperglycemia. These symptoms may be subtle, especially in young children. For this reason, blood glucose needs to be checked more frequently in young children.

#### **Continuous Glucose Monitors**

Some children use a continuous glucose monitor (CGM) to record blood glucose levels. CGM results must be confirmed with blood glucose tests. Parents/guardians should discuss CGM management with child care providers. A basic understanding of CGM use is warranted, but detailed management should not be expected of child care providers. Safe monitoring must include the following recommendations:

- 1. Avoid community exposure to sharps and other medical waste.
- 2. Minimize trauma to the finger or relevant lancing site.

Blood lancing devices must not be reused, point-of-care devices should only be used for the designated child, and child care providers should use gloves when testing (8). The ADA's Safe at School program is a helpful resource to assist schools (18).

#### Insulin Administration

Children with diabetes who attend child care programs must have access to insulin, glucagon, and other medications to safely participate in the programs. Training child care staff on insulin administration is a critical component of diabetes management, especially for those caring for children who participate in daylong (4- to 8-h) programs and who will likely need insulin administered during the programs. For resources, please see RESOURCES for ADA's Safe at School program.

#### Glucagon

Glucagon may be indicated if a child has severe hypoglycemia and is unable to consume glucose or is having a hypoglycemic seizure. Although a glucagon kit requires a prescription, any individual may administer glucagon. Child care staff should be trained in the administration of glucagon or, if indicated, mini-dose glucagon (19). It is also important to ensure that the glucagon kits are not expired (5).

#### **Key Points**

 The DCCT showed that improved glycemic control decreases long-term diabetes complications in adolescents (≥13 years of age) and adults and helped establish intensive therapy as the standard of care. Although young children were not included in the study, the same principles apply to this age-group.

- Regardless of the amount of time the child spends in the child care setting, staff should monitor carbohydrate intake and understand the impact of carbohydrates and physical activity as set out in the child's DMMP.
- Trained child care staff should be available to meet the child's basic diabetes needs, including the recognition and treatment of hypo- and hyperglycemia, blood glucose monitoring, and insulin and glucagon administration.
- Diabetes management requirements may vary depending on the length, frequency, and activities of the child care program.
- The key diabetes management priority for younger children is the prevention, recognition, and treatment of hypo- and hyperglycemia to keep the child safe and healthy.

#### **DMMP**

The child's written care plan, such as the DMMP, facilitates appropriate diabetes management and is essential to achieving optimal glycemic control. The DMMP contains the medical orders that are the basis for the provision of care in the child care setting and is the child's individual care plan. It is developed by the child's own diabetes health care provider with input from the parent/ guardian. A sample DMMP for the child care setting may be found at the end of this document or at www.diabetes .org/childcare. The DMMP should address the specific needs of the child and provide instructions for each of the following:

- Blood glucose monitoring, including the frequency and circumstances requiring blood glucose checks and the use of CGM systems;
- Insulin administration including doses and administration times prescribed for specific blood glucose levels and for carbohydrate intake, the storage of insulin, and the use of the prescribed insulin delivery device, including syringe, pen, or pump;
- Symptoms and treatment of hypoglycemia, including the administration of glucagon;
- 4. Symptoms and treatment of hyperglycemia, including insulin administration;
- Urine or blood ketone checks and appropriate actions based on a child's ketone level.

The child care program needs to coordinate and arrange diabetes education provided by a diabetes health care professional and/or the parent/ guardian at an appropriate level and with proper considerations for the child care staff. All staff members responsible for the child should have a basic knowledge of the child's diabetes, understand basic diabetes management, and know who to contact for help. Designated staff members who will be performing diabetes care tasks need advanced diabetes education that includes blood glucose monitoring, insulin and glucagon administration, monitoring of carbohydrate intake and physical activity, and recognizing and treating hyperglycemia (monitoring for excessive urination or thirst, allowing bathroom privileges, and administering insulin) and hypoglycemia (monitoring for sleepiness, lethargy, shakiness, or other symptoms and providing appropriate carbohydrate sources even if outside the allotted snack or meal time frames). Emergency treatment, including glucagon administration, should also be taught with clear instructions for the next steps if the interventions are unsuccessful (Table 2).

# LAWS PROTECTING CHILDREN WITH DIABETES

Federal antidiscrimination laws, including the Americans with Disabilities Act (20) and Section 504 of the Rehabilitation Act of 1973 (Section 504) (21), prohibit discrimination on the basis of disability. The Individuals with Disabilities Education Act (IDEA) requires prekindergarten programs to identify children with disabilities and to provide them with a free and appropriate education (22).

The Americans with Disabilities Act prohibits discrimination against people with disabilities by places of public accommodation, including camps and child care programs. This includes even a home-based setting, if the program is open to the public. Programs operated by religious organizations, such as a child care program run by a church, are not subject to the nondiscrimination obligations under federal law unless the program receives federal funds. Child care providers with obligations under the Americans with Disabilities Act must make reasonable

Table 2—Diabetes care tasks prescribed by DMMP to be provided by child care staff				
Task	Frequency	Equipment/supplies (provided by parent/guardian)		
Blood glucose monitoring	Before food intake and physical activity and when low or high blood glucose is suspected	Blood glucose meter, lancet, lancing device, test strips, CGM*		
Insulin administration	Before or after food intake and to treat high blood glucose	Insulin, delivery device (pump, pen, syringe)		
Food intake scheduling and monitoring	Snacks and meals provided and/or monitored to ensure food consumption is in accordance with insulin dosing	Food, carbohydrate information		
Hypoglycemia treatment	Awareness that unusual behaviors after physical activity or insulin administration may signify hypoglycemia	Quick-acting carbohydrate and glucagon		
Hyperglycemia treatment	Awareness that increased urination or drinking may signify hyperglycemia	Noncarbohydrate-containing liquid, insulin		
Ketone monitoring	Check ketones if repeated blood glucose tests show elevation above target range or if the child is ill	Urine or blood ketone strips, ketone monitor		

modifications to their policies and practices to enable a child with a disability, such as diabetes, to fully participate in the program unless the modifications impose an "undue hardship" or cause a "fundamental alteration" to the nature of the program (20,21,23). The child care program must conduct an individual assessment to determine whether or not it can meet the child's needs without imposing undue hardship or fundamentally altering the program.

Section 504 prohibits discrimination on the basis of disability by any entity receiving federal funds—including religious organizations. Types of programs covered by Section 504 might include after-school child care programs offered by a public school system and child care programs run by universities. The obligations of a child care program subject to Section 504 are very similar to those obligations under the Americans with Disabilities Act, including a requirement to conduct an individualized assessment of a child's needs. Both the Americans with Disabilities Act and Section 504 require programs to provide disability-related accommodations if they are necessary and reasonable. Many of the needed accommodations can be provided by the child care program without significant costs. Some accommodations that may be needed include having a trained employee who can perform blood glucose checks, administer insulin and glucagon, recognize and promptly treat hypo- and hyperglycemia, and make sure the child consumes needed carbohydrates.

In addition, many states have laws that impact the provision of diabetes care in the child care setting. Even though federal laws provide protection for children with disabilities, such as diabetes, state laws, regulations, or policies and guidelines often affect whether nonnursing staff in the child care setting can administer medication, including insulin and glucagon, to a child with diabetes. Some states have specific child care rules that place requirements on child care programs to provide care to children with chronic illness, specify how staff must be trained, or specify whether and how medication may be administered to children. State laws cannot, however, lessen a child care program's obligations under federal law.

Children with diabetes in child care programs still face discrimination despite the protections and requirements of federal and state laws. For example, some child care programs refuse to enroll a child with diabetes, and some programs refuse to allow a newly diagnosed child back into the program. Some centers will enroll a child only if the parent/guardian agrees to come to the center to provide needed care. Many other programs have "no injection" or "no medication" policies that do not consider the individual child's needs. This type of treatment jeopardizes the health and safety of the child, and such blanket policies are unlawful. For more information and resources to help with diabetes management in the child care setting or if a child is experiencing discrimination in the child care setting, call 1-800-DIABETES (342-2382) or go to www.diabetes.org/childcare.

#### **Key Points**

- Federal and some state laws provide protections for children with diabetes in the child care setting.
- Despite federal and state laws, children in child care programs still face discrimination, jeopardizing their health and safety or making it difficult for them to enroll in child care.

#### **KEY PRINCIPLES**

Here, we reiterate the discussed concepts; however, the section is structured so that it outlines the legal principles and the roles and responsibilities of the individuals involved.

- 1. Acceptance for enrollment. Child care programs should not deny admission to a child based on diabetes or the need for diabetes care. The parent/guardian should share strategies for overcoming challenges specific to their child, such as poor communication or resistance to diabetes care tasks. If a child care center refuses to enroll or provide diabetes care to a child, it is important to determine the center's concerns and see if the concerns can be addressed through education and training.
- Written care plans. As stated previously, a written care plan, such as an individualized DMMP, should be developed by the child's personal diabetes health care team in collaboration with the parent/guardian.
- Provision of care by child care staff. After consulting with the parent/ guardian and reviewing the child's

current DMMP, the child care program should perform an assessment of the child's needs to determine how it will provide diabetes care. An identified group of child care staff who are willing to provide direct care for the child with diabetes should receive advanced training from a diabetes health care professional or the parent/guardian on routine and emergency diabetes care so that at least one staff member is always available to provide diabetes care.

- 4. Basic training for all staff in a child care setting. The child care provider should work with the parents/ guardians to arrange for training by a diabetes health care professional or the parent/guardian in basic diabetes education and identify additional training resources as needed. All child care staff members who are responsible for the child with diabetes should receive basic training that provides:
  - An overview of diabetes that includes information on how to recognize and respond to hypo- and hyperglycemia and
  - Instruction on identifying medical emergencies and contacting the right personnel with questions or in case of an emergency.
- 5. Advanced training for a small group of child care staff. Advanced training provided by a diabetes health care professional or parent/guardian should include:
  - All components of basic diabetes training as listed above;
  - Instruction on how to perform blood glucose monitoring, insulin and glucagon administration, and urine and/or blood ketone checks;
  - Training on the recognition and treatment of hypo- and hyperglycemia; and
  - Basic carbohydrate counting/ monitoring carbohydrates.
- 6. Instruction should include demonstration of the care tasks and a plan for ongoing training. The number of staff members trained should be sufficient to ensure that at least one staff member who can provide routine and emergency diabetes care, such as insulin and glucagon administration, will be available at all times.

7. Participation in diabetes care should be allowed for capable children. Child care programs should support the child in his or her development by allowing participation in diabetes tasks in accordance with the child's competencies, as outlined in the DMMP. A preschooler may be able to participate in his or her diabetes care by checking blood glucose or choosing a fingerprick or injection site, all under the supervision of an adult.

#### **Key Points**

- Child care centers should not deny admission on the basis of a child having diabetes.
- A written care plan with medical orders, such as a DMMP, should be provided by the diabetes care provider and parent/guardian to the child care setting.
- All child care staff responsible for the child with diabetes should receive basic training.
- Advanced, child-specific training should be provided to a small number of child care staff, and there should be at least one trained staff member available to provide care at all times.

## RESPONSIBILITIES OF STAKEHOLDERS

- 1. The parent/guardian should provide the child care program with:
  - Information about diabetes management and training resources if needed
  - A completed written care plan, such as a DMMP, signed by a child's diabetes health care provider
  - Current and accurate emergency contact information including phone numbers for the parent/guardian and the child's diabetes health care provider
  - All materials, equipment, supplies, insulin/medication, and food needed for diabetes management and ongoing monitoring of supplies for replenishment or replacement if expired
  - An appropriate container for the disposal of sharps
  - A method of communication between the parent/guardian and the child care program, such as a logbook or electronic diabetes management application

- Basic diabetes training (if needed) for all child care staff members who have responsibility for the child and advanced child-specific training for the designated child care staff members who are responsible for providing regular daily care to the child
- Information about factors that may impact blood glucose levels, such as the child's daily activity level, food intake prior to arrival at the center, and whether the child is experiencing an illness
- Consent to release confidential health information so that the child care program can communicate directly with the child's diabetes health care provider and direction on when such communication is appropriate

#### 2. The child care program should:

- Understand federal and state laws and regulations as they apply to children with diabetes
- Assess how the child care program will provide routine and emergency care after consulting with parent/guardian and reviewing the DMMP
- Recruit and designate staff who will be responsible for the provision of diabetes care to the child
- Work with parents/guardians to arrange for training for all staff members who have responsibility for the child and advanced childspecific training for designated child care staff members who are responsible for providing daily care to the child
- Provide secure and immediate accessibility of diabetes materials, equipment, supplies, insulin/medication, and food to trained staff members
- Provide support to all families of children in its care who are faced with language barriers and limited resources and be aware of and share community resources for families of children with diabetes
- Maintain accurate documentation of all diabetes care provided to a child in its care
- Collaborate with parents/guardians and/or diabetes health care providers to obtain current information about the care of children with diabetes

- · Regularly communicate blood glucose results, insulin administration, treatment of hypo- and hyperglycemia, food intake, and physical activity using a logbook, electronic application, or other method provided by the parent/ guardian
- Treat children with diabetes the same as other children, except to meet their diabetes needs
- · Respect the child's and family's confidentiality and right to privacy
- 3. The child's diabetes health care provider should provide:
  - A completed and signed written care plan containing medical orders, such as a DMMP, with updates as needed
  - In conjunction with the parent/ guardian, basic and advanced training to child care staff
  - Availability to respond to questions about the child's care with parental consent
  - Ongoing diabetes expertise and guidance as needed
  - · Advocacy, as needed, to ensure a child's needs are met while in the child care setting

#### **Key Points**

• Parents/guardians, child care staff, and the child's health care provider all play important roles in ensuring appropriate care of the child with diabetes in a child care program. Each has specific roles and responsibilities to ensure that the child is maintained in a healthy and safe child care environment.

#### CONCLUSION

It is well understood that young children with diabetes have unique needs. Young children require a carefully thought-out, proactive diabetes care plan and not a reactive one (i.e., crisis management) that must be developed with the health care provider, parents/ guardians, and child care staff. Unfortunately, despite all the best efforts of the parents/guardians, care may be suboptimal in the child care setting. For those instances, there are federal laws that protect the rights of the young child. Violation of these rights may be subject to legal action. Recommended resources for parents are listed below. We encourage parents/guardians of young children with diabetes to share this Position Statement with their child care providers. Ensuring the long-term health of and providing the best care to these young children should be of paramount importance.

#### **RESOURCES**

- American Diabetes Association. Child Care Setting tools (including Child Care DMMP): www.diabetes.org/ childcare and www.diabetes.org/ forparentsandkids.
- American Diabetes Association. Safe at School resources and information: www.diabetes.org/safeatschool.
- American Diabetes Association. Diabetes Care Tasks at School: What Key Personnel Need to Know: www.diabetes.org/ schooltraining.
- National Diabetes Education Program. Helping the Student with Diabetes Succeed: A Guide for School Personnel (2010): http://ndep.nih.gov/media/ Youth\_NDEPSchoolGuide.pdf.

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Child Care Diabetes Medical Management Plan  Name of Child: DOB: Dates Plan in Effect: Parent or Guardian Name(s)/Number(s): Diabetes Care Provider Name/Number: Dates  Location of diabetes supplies at child care facility:  Blood Glucose Monitoring  Target range for blood glucose is:   80-180   Other When to check blood glucose:   before breakfast   before lunch   before dinner   before snacks
Name of Child:
Parent or Guardian Name(s)/Number(s):
Diabetes Care Provider Name/Number:
Diabetes Care Provider Signature:
Location of diabetes supplies at child care facility:  Blood Glucose Monitoring  Target range for blood glucose is:   Other
Blood Glucose Monitoring  Target range for blood glucose is:   Other
Target range for blood glucose is: □ 80-180 □ Other
When to check blood glucose: □ before breakfast □ before lunch □ before dinner □ before snacks
When to do extra blood glucose checks: □ before exercise □ after exercise □ when showing signs of low blood glucose
$\square$ when showing signs of high blood glucose $\square$ other
Insulin Plan: Please indicate which type of insulin regimen this child uses (check one):
☐ Insulin Pump ☐ Multiple Daily Injections ☐ Fixed Insulin Doses
Specific information related to each insulin regimen/plan is included below for this child.
Type of insulin used at child care (check all that apply): ☐ Regular ☐ Apidra ☐ Humalog ☐ Novolog ☐ NPH
☐ Lantus ☐ Levemir ☐ Mix ☐ Other
Plan A: Insulin Pump* Plan B: Multiple Daily Injections C: Fixed Insulin Doses
1. Always use the insulin pump bolus
wizard:   Yes  No  Long-acting insulin at acting insulin?   Yes  No
If no, use Insulin:Carbohydrate Ratio and 🗆 Yes 🗆 No If yes, give child units of
Correction Factor dosage on Plan B. 2. Follow blood glucose monitoring insulin at
2. Blood glucose must be checked before plan above. 2. Insulin correction dose at child care
the child eats and will (check one): 3. Use insulin for meals ( insulin)?
☐ Be sent to the pump by the meter and snacks. Insulin dose for food is ☐ Yes☐ No
□ Need to be entered into the pump unit(s) for meals <b>OR</b> 3. If blood glucose is above target, add
3. The insulin pump will calculate the unit(s) for every grams correction dose to:
correction dose to be delivered <b>before</b> carbohydrate. □ <b>Breakfast</b> □ <b>Snack</b> the meal/snack. □ <b>Lunch</b> □ <b>Snack</b>

#### 4. After the meal/snack, enter the total 4. If blood glucose is above target, add number of carbohydrates eaten at correction dose to: that meal/snack. The insulin pump will □ Breakfast □ Snack calculate the insulin dose for the meal. ☐ Lunch □ Snack ☐ Other: \_ 5. Contact parent/guardian with any Use the following correction factor concerns. \_\_\_\_ or this scale: For a list of definitions of terms used in \_\_\_\_ units if BG is \_\_\_\_ to \_\_\_\_ this document, please see the Diabetes \_\_\_\_ units if BG is \_\_\_\_ to \_\_\_\_ Dictionary. \_\_\_\_ units if BG is \_\_\_\_ to \_\_\_\_ \*Providers should complete \_\_\_ units if BG is \_\_\_\_ to \_\_\_ Insulin:Carbohydrate ratio and Correction dosage under Plan B section for ALL pump users.

#### Only add correction dose if it has been 3 hours since the last insulin administration.

C: Fixed Insulin Doses
1. Child will receive a fixed dose of long
acting insulin? 🗆 Yes 🗆 No
If yes, give child units of
insulin at
2. Insulin correction dose at child care
( insulin)?
□ Yes□ No
3. If blood glucose is above target, add
correction dose to:
☐ Breakfast ☐ Snack
☐ Lunch ☐ Snack
☐ Other:
Use the following correction factor
or the following
scale:
units if BG is to
Only add correction dose if it has been 3 hours since the last insulin

#### **Managing Very Low Blood Glucose**

# Hypoglycemia Plan for Blood Glucose less than mg/dL

- 1. Give 15 grams of fast-acting carbohydrate.
- 2. Recheck blood glucose in 15 minutes.
- 3. If still below 70 mg/dL, offer 15 grams of fast-acting carbohydrate, check again in 15 minutes.
- 4. When the child's blood glucose is over 70, provide 15 grams of carbohydrate as snack. Do not give insulin with this snack.
- 5. **Contact the parent/guardian** any time blood glucose is less than \_\_\_\_\_ mg/dL at child care.

<b>Usual symptoms</b>	of	hypoglycemia	for	this	child	include
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☐ Shaky	☐ Fast heartbeat	☐ Sweating
□ Anxious	☐ Hungry	☐ Weakness/Fatigue
☐ Headache	☐ Blurry vision	☐ Irritable/Grouchy
☐ Dizzy	☐ Other	

- 1. If you suspect low blood glucose, check blood glucose!
- 2. If blood glucose is below \_\_\_\_\_, follow the plan above.
- 3.If the child is unconscious, having a seizure (convulsion) or unable to swallow:
  - Give glucagon. Mix liquid and powder and draw up to the first hash mark on the syringe. Then inject into the thigh. Turn child on side as vomiting may occur.
  - If glucagon is required, administer it promptly. Then, call 911 (or other emergency assistance). After calling 911, contact the parents/guardians. If unable to reach parent, contact diabetes care provider.

#### **Managing Very High Blood Glucose**

# Hyperglycemia Plan for Blood Glucose higher than \_\_\_\_\_ mg/dL

#### Usual symptoms of hyperglycemia for this child include:

- □ Extreme thirst
   □ Very wet diapers, accidents
   □ Hungry
   □ Warm, dry, flushed skin
   □ Tired or drowsy
   □ Headache
   □ Blurry vision
   □ Vomiting\*\*
- $\square$  Fruity breath  $\square$  Rapid, shallow breathing
- ☐ Abdominal pain ☐ Unsteady walk (more than typical)
  \*\*If child is vomiting, contact parents immediately

#### Treatment of hyperglycemia/very high blood glucose:

- 1. Check for ketones in the:
  - ☐ urine ☐ blood (parent will provide training)
- 2. If ketones are moderate or large, contact parent. If unable to reach parent, contact diabetes care provider for additional instructions.
  - Contact parent if ketones are trace or small:  $\Box$  Yes  $\quad \Box$  No
- 3. Children with high blood glucose will require additional insulin if the last dose of insulin was given 3 or more hours earlier. Consult the insulin plan above for instructions. If still uncertain how to manage high blood glucose, contact the parent.
- 4. Provide sugar-free fluids as tolerated.
- 5. You may also:
  - $\square$  Provide carbohydrate-free snacks if hungry
  - ☐ Delay exercise
  - $\hfill \Box$  Change diapers frequently/give frequent access to the bathroom
  - $\square$  Stay with the child

#### **Diabetes Dictionary**

**Blood glucose** - The main sugar found in the blood and the body's main source of energy. Also called blood sugar. The **blood glucose level** is the amount of glucose in a given amount of blood. It is noted in milligrams in a deciliter, or mg/dL.

**Bolus** - An extra amount of insulin taken to lower the blood glucose or cover a meal or snack.

**Bolus calculator** - A feature of the insulin pump that uses input from a pump user to calculate the insulin dose. The user inputs the blood glucose and amount of carbohydrate to be consumed, and the pump calculates the dose that can be approved by the user.

**Correction factor** – The drop in blood glucose level, measured in milligrams per deciliter (mg/dL), caused by each unit of insulin taken. Also called **insulin sensitivity factor**.

**Diabetic ketoacidosis (DKA)** – An emergency condition caused by a severe lack of insulin, that results in the breakdown of body fat for energy and an accumulation of ketones in the blood and urine. Signs of DKA are nausea and vomiting, stomach pain, fruity breath odor and rapid breathing. Untreated DKA can lead to coma and death.

**Fixed-dose regimen** - Children with diabetes who use a fixed-dose regimen take the same "fixed" doses of insulin at specific times each day. They may also take additional insulin to correct **hyperglycemia**.

**Glucagon** - A hormone produced in the pancreas that raises blood glucose. An injectable form of glucagon, available by prescription, is used to treat severe hypoglycemia or severely low blood glucose.

**Hyperglycemia** - Excessive blood glucose, greater than 240 mg/dL for children using an insulin pump and greater than 300 mg/dL for children on insulin injections. If untreated, the patient is at risk for **dlabetic ketoacidosis (DKA)**.

**Hypoglycemia** - A condition that occurs when the blood glucose is lower than normal, usually less than 70 mg/dl.. Signs include hunger, nervousness, shakiness, perspiration, dizziness or light-headedness, sleepiness, and confusion. If left untreated, hypoglycemia may lead to unconsciousness.

**Insulin** - A hormone that helps the body use glucose for energy. The beta cells of the pancreas make insulin. When the body cannot make enough insulin, it is taken by injection or through use of an insulin pump.

**Insulin pump** - An insulin-delivering device about the size of a deck of cards that can be worn on a belt or kept in a pocket. An insulin pump connects to narrow, flexible plastic tubing that ends with a needle inserted just under the skin. Pump users program the pump to give a steady trickle or constant (basal) amount of insulin continuously throughout the day. Then, users set the pump to release bolus doses of insulin at meals and at times when blood glucose is expected to be higher. This is based on programming done by the user.

**Ketones** - A chemical produced when there is a shortage of insulin in the blood and the body breaks down body fat for energy. High levels of ketones can lead to **diabetic ketoacidosis** and coma.

**Multiple daily injection regimen** - Multiple daily insulin regimens typically include a basal, or long-acting, insulin given once per day. A short-acting insulin is given by injection with meals and to correct hyperglycemia, or elevated blood glucose, multiple times each day.

**Type 1 diabetes** - Occurs when the body's immune system attacks the insulin-producing beta cells in the pancreas and destroys them. The pancreas then produces little or no insulin. Type 1 diabetes develops most often in young people but can appear in adults. It is one of the most common chronic diseases diagnosed in childhood.

Physician Signature









# Diabetes Care in the School Setting: A Position Statement of the American Diabetes Association

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Diabetes is one of the most common chronic diseases of childhood (1). There are approximately 200,000 individuals  $<\!20$  years of age with diabetes in the U.S. (2). The SEARCH for Diabetes in Youth (SEARCH) study recently reported that 1.93 per 1,000 (aged  $<\!20$  years) were diagnosed with type 1 diabetes, an increase of 21% from 2001 to 2009. Increases in the prevalence of type 1 diabetes were seen in all ethnic groups, but non-Hispanic whites were disproportionately affected. Because type 2 diabetes rarely occurs in younger children, its prevalence in the population aged  $<\!20$  years is not readily available. For type 2 diabetes in youth between 10 and 20 years of age, the SEARCH study reported a prevalence of 0.46 per 1,000 youth of all ethnicities, an increase of 31% from 2001 to 2009 (3). These statistics demonstrate the rising prevalence of diabetes in children and the increased need for diabetes management.

The majority of young people with diabetes spend many hours at school and/or in some type of child care program. Trained and knowledgeable staff are essential to provide a safe school and child care environment for children with diabetes. This includes the provision of care during the school day, field trips, and all school-sponsored activities in the school setting and in preschool, day care, and camp programs in the child care setting. Staff play a critical role in helping to reduce the risk of short- and long-term complications of diabetes and ensuring that children are well-positioned for academic success and normal growth and development. The child's parents/guardians and health care provider(s) should work together to provide school systems and child care providers with the information necessary to enable children with diabetes to participate fully and safely in the school and child care setting experiences (4–6).

The purpose of this position statement is to provide the diabetes management recommendations for *students with diabetes in the elementary and secondary school settings* based on the American Diabetes Association's (ADA's) "Standards of Medical Care in Diabetes—2015" (6) and "Type 1 Diabetes Through the Life Span: A Position Statement of the American Diabetes Association" (7). For information on young children aged <5 years, ADA's position statement "Care of Young Children With Diabetes in the Child Care Setting" (8) should be reviewed for specific recommendations for settings such as day care centers, preschools, camps, and other programs.

#### DIABETES AND THE LAW

Federal laws that protect children with diabetes include Section 504 of the Rehabilitation Act of 1973 (9), the Individuals with Disabilities Education Act (10), and the Americans with Disabilities Act (11). Under Section 504 and the Americans with Disabilities Act, diabetes is considered a disability. It is illegal for schools to discriminate against students with disabilities including diabetes. Any school that receives federal funding—public, charter, private, and parochial schools and postsecondary institutions—or any facility considered open to the public must reasonably accommodate the special needs of students with diabetes. Indeed, federal law requires an individualized assessment of any child with diabetes. The required accommodations should be documented in a written plan developed under the applicable federal law such as a Section 504 Plan or Individualized Education Program (IEP).

In addition to federal laws, many diabetes-specific state laws provide protections that enable school staff to provide care. Some states have laws that prevent non-nurse school staff from administering medications such as insulin and glucagon.

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Regardless of state laws, federal law requirements must always be met so that students with diabetes have access to the care they need to be safe and able to fully participate in all schoolsponsored activities such as beforeschool breakfast programs, recess, after-school clubs, sports, detention, and school dances (12–14).

These laws help to ensure that the needs of students with diabetes are provided for within the usual school setting with as little disruption to the school's and the student's routine as possible. The laws also ensure that the student is able to fully participate in all school activities (13-15). Despite these protections, students with diabetes still face discrimination at school. For example, students may not receive the assistance necessary to monitor blood glucose and administer insulin and may be prohibited from eating needed snacks in the classroom. Some schools may require a student to attend a different school from his or her assigned school in order to receive the diabetes care he or she needs. The ADA works to prevent such discriminatory practices and to ensure the safe and fair treatment of students with diabetes in the school setting (15–18).

#### **Key Points**

- Federal and some state laws provide legal protections for students with diabetes in the school setting.
- Some states have laws preventing nonnurse school staff from administering medications such as insulin and glucagon.
- Required accommodations should be documented in a written plan under applicable federal law.
- Despite federal and state laws, students with diabetes still face discrimination, potentially jeopardizing their health and safety and making it difficult for them to safely participate in school-sponsored activities.
- The ADA works to ensure the safe and fair treatment of children with diabetes in the school setting.

#### DIABETES CARE IN SCHOOLS

Appropriate diabetes care in the school is necessary for the student's immediate safety, long-term well-being, and optimal academic performance. The Diabetes Control and Complications Trial (DCCT) showed a significant link between blood

glucose control and later development of diabetes complications in children as young as 13 years of age, with improved glycemic control decreasing the risk of complications (19,20). To achieve glycemic control, a child must check blood glucose levels frequently, follow a healthy meal plan, take insulin/medications, and engage in regular physical activity. Insulin is administered by multiple daily injections or with an insulin infusion pump. Crucial to achieving glycemic control is an understanding of the effect of diet, physical activity, and insulin on blood glucose levels.

To facilitate appropriate care, the school nurse and other school staff must have an understanding of diabetes and be trained to manage daily diabetes-specific tasks as well as to manage diabetes emergencies (4,5,8,21–31). Knowledgeable and trained school staff are essential if the student is to avoid the immediate health risks of low and high blood glucose and to achieve the glycemic control required to decrease risks for later development of diabetes complications (5,23). Studies have shown that the majority of school staff members have an inadequate understanding of diabetes (23,24). Consequently, diabetes education must be targeted toward teachers and other school staff who interact with the student, including school nurses, administrators, coaches, health aides, bus drivers, secretaries, etc. (4,25,26,28). Current ADA recommendations and resources regarding appropriate care for students with diabetes are available to all school staff (4,26).

#### **Key Points**

- Students with diabetes must receive appropriate care in the school setting to reduce the risk of short- and longterm complications.
- The school nurse and other school staff need to be trained to meet the needs of students with diabetes.

# GENERAL GUIDELINES FOR DIABETES CARE AT SCHOOL

Diabetes Medical Management Plan An individualized Diabetes Medical Management Plan (DMMP) should be developed by the student's health care provider in collaboration with the student and parent/guardian to set out the student's diabetes management needs during the school day and at all schoolsponsored activities. Inherent in this process are delineated responsibilities

assumed by all parties, including the parent/guardian, the school staff, and the student (4,27,32). These responsibilities are outlined in this position statement. In addition, the DMMP should be used as the basis for the development of written education plans such as the Section 504 Plan or the IEP. The DMMP should address the specific needs of the student and provide specific instructions for each of the following:

- Blood glucose monitoring, including the frequency and circumstances requiring blood glucose checks, and use of continuous glucose monitoring, smartphone and smartwatch applications, or other technology, if applicable.
- Insulin administration (if necessary)
  using the student's preferred insulin
  delivery system, including doses/
  injection times prescribed for specific
  blood glucose values and for carbohydrate intake, the storage of insulin,
  and, when appropriate, physician authorization of parent/guardian adjustments to insulin dosage.
- 3. Meals and snacks, including food content, amounts, and timing.
- Symptoms and treatment of hypoglycemia (low blood glucose), including the administration of glucagon if recommended by the student's health care provider.
- Symptoms and treatment of hyperglycemia (high blood glucose), including the administration of insulin if recommended by the student's health care provider.
- Checking for ketones and appropriate actions to take for abnormal glucose and ketone levels, if requested by the student's health care provider.
- 7. Participation in physical activity.
- Emergency evacuation/school lockdown instructions and emergency contacts and plans.

A sample DMMP (http://professional .diabetes.org/DMMP) may be accessed online and customized for each individual student. For detailed information on the symptoms and treatment of hypoglycemia and hyperglycemia, refer to *Medical Management of Type 1 Diabetes* (33). A brief description of diabetes targeted to school staff is included in the Supplementary Data; it may be helpful to include this information as an introduction to the DMMP.

## Responsibilities of the Various Stakeholders

# The Parent/Guardian Should Provide the School With the Following:

- 1. All materials, equipment, supplies (meter, test strips, lancets, lancing device), insulin (backup syringes, pump supplies, etc., if needed), and other medication necessary for diabetes management, including blood glucose monitoring, insulin administration (if needed), glucose tablets, glucagon emergency kit, urine or blood ketone monitoring, and food/snacks. The parent/guardian is responsible for the maintenance of the blood glucose monitoring equipment (i.e., cleaning and performing controlled testing per the manufacturer's instructions) and must provide materials necessary to ensure proper handling and disposal of materials. An appropriate recordkeeping system should be maintained at school, enabling staff or student to record blood glucose and ketone results; blood glucose values should be transmitted to the parent/guardian for review and presented in the DMMP. Some students maintain a record of blood glucose results in the meter memory or through other electronic
- 2. The DMMP completed and signed by the student's health care provider.
- Supplies to treat hypoglycemia, including glucose tablets or a source of quick-acting carbohydrate and a glucagon emergency kit.
- Information about diabetes and the performance of diabetes-related tasks such as blood glucose monitoring and insulin administration.
- Current emergency phone numbers for the parent/guardian and the student's health care provider so that the school, with parental consent, can contact these individuals with diabetes-related questions and/or during emergencies.
- 6. Information about the student's meal/snack schedule. The parent should work with the school before the beginning of the school year or before the student returns to school after the diagnosis to coordinate this schedule with that of the other students as closely as possible. Instructions should be given for situations when food is provided during school parties and other activities.

7. In most locations, and increasingly, a signed release of confidentiality limited to diabetes-related care will be required so that the health care provider can communicate with the school. Copies should be retained both at the school and in the health care provider's offices.

#### The School Should Provide the Following:

- Opportunities for the appropriate level of ongoing training and diabetes education for the school nurse and school district health care coordinators.
- 2. Training for school staff as follows (4):
  - a. Level 1 training for all school staff members, which includes a basic overview of diabetes, typical needs of a student with diabetes, recognition of hypoglycemia and hyperglycemia, and the contact information for help.
  - b. Level 2 training for school staff members who have responsibility for students with diabetes, which includes all content from level 1 plus recognition and treatment of hypoglycemia and hyperglycemia and required accommodations for those students.
  - c. Level 3 training for a small group of school staff members who will perform student-specific routine and emergency care tasks such as blood glucose monitoring, insulin administration, and glucagon administration when a school nurse is not available to perform these tasks. This will also include level 1 and level 2 training.
- Immediate accessibility to the treatment of hypoglycemia by a knowledgeable adult. The student should remain supervised until appropriate treatment has been administered, and the treatment should be available as close to where the student is as possible.
- 4. Accessibility to scheduled insulin at times set out in the student's DMMP and immediate accessibility to treatment for hyperglycemia including insulin administration as set out by the student's DMMP.
- A location at school that allows privacy during blood glucose monitoring and insulin administration, if desired by the student and family, or permission for the student to

- check his or her blood glucose level and take appropriate action to treat hypoglycemia and hyperglycemia in the classroom or anywhere the student is in conjunction with a school activity, if indicated in the student's DMMP.
- School nurse and trained school staff who can check blood glucose and ketones and administer insulin, glucagon, and other medications as indicated by the student's DMMP.
- 7. School nurse and trained school staff responsible for the student who are aware of the student's meal and snack schedule and work with the parent/guardian to synchronize this schedule with that of the other students. This individual will also notify the parent/guardian in advance of any expected changes in the school schedule that affect the student's meal times or exercise routine and will remind young children of snack times.
- Permission for self-sufficient and capable students to carry equipment, supplies, medication, and snacks and to perform diabetes management tasks anywhere and at any time.
- Permission for the student to have smartphone or other technology and direct communication access to reach the parent/guardian and health care provider and document treatment.
- Permission for the student to see the school nurse and other trained school staff as often as requested.
- Permission for the student to eat a snack anywhere, including the classroom or the school bus, if necessary to prevent or treat hypoglycemia.
- 12. Permission to miss school without consequences for illness, diabetes management, and required medical appointments to monitor the student's diabetes management. This should be an excused absence with a doctor's note, if required by usual school policy.
- 13. Permission for the student to use the restroom and have access to fluids (i.e., water) as necessary.
- An appropriate location for insulin and/or glucagon storage, if necessary.

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- 15. A plan for the disposal of sharps based on an agreement with the student's family, local ordinances, and Standard Precautions.
- Information on serving size and caloric, carbohydrate, and fat content of foods served in the school (34).

The school nurse should be the key coordinator and provider of care. The school nurse and/or other qualified health care professional with expertise in diabetes should work with the school principal or other school administrator to identify school personnel who are willing and volunteer to be trained to provide care, and to coordinate the training of an adequate number of school staff as specified above. It is the school's responsibility to provide appropriate training to an adequate number of school staff on diabetes-related tasks and in the treatment of diabetes emergencies. This training should be provided by the school nurse or another qualified health care provider with expertise in diabetes. The school must ensure that if the school nurse is not present, at least one trained school employee be available to perform these procedures in a timely manner while the student is at school; on field trips; participating in schoolsponsored extracurricular activities such as prebell breakfast programs, intramural sports, after-school clubs, detention, and school dances; and on transportation provided by the school. This is needed in order to enable full and safe participation in school activities (4,23). These school staff need not be health care professionals (4,14,22,28,30). Parents/caregivers should be made aware of the individuals who are being informed about the student's diabetes diagnosis (and permission sought if possible) in an effort to protect privacy.

#### Student's Role and Responsibilities

A student should be allowed to provide his or her own diabetes care at school to the extent that is appropriate based on the student's development and his or her experience with diabetes. The extent of the student's ability to participate in diabetes care should be agreed upon by the parent/guardian, the student's health care provider, and school staff. The ages at which a child is able to successfully perform self-care tasks vary and depend on the individual. A child's capabilities and willingness to provide self-care should be assessed and respected.

- 1. Young children (<5 years of age): unable to perform diabetes tasks independently and will need an adult to provide all aspects of diabetes care. Many younger children will have difficulty in recognizing hypoglycemia, so it is important that school staff recognize and provide prompt treatment. However, children in this age range can often choose which finger to prick and select an injection site and are generally cooperative. ADA's position statement on child care "Care of Young Children With Diabetes in the Child Care Setting" (8) should be reviewed for more information.
- 2. Elementary students: depending on the duration of diabetes and level of maturity, may be able to perform their own blood glucose checks, but usually will require supervision. Older elementary students are generally beginning to self-administer insulin with supervision and understand the effect of insulin, physical activity, and nutrition on blood glucose levels. Unless the child has hypoglycemia unawareness, he or she should usually be able to let an adult know when experiencing low blood glucose.
- 3. Middle school— and high school— aged students: are usually able to self-manage their diabetes depending on the duration of diabetes and level of maturity but will always need help when experiencing severe hypoglycemia. Independence in older youth should generally be encouraged to enable the student to engage in his or her decisions about his or her own care.

Students' competence in and capability of performing diabetes-related tasks are presented in the DMMP and then adapted to the school setting. Individuals with diabetes of any age may require assistance to perform a blood glucose check when blood glucose is low. In addition, individuals experiencing low blood glucose may need a reminder to eat or drink and should never be left unsupervised until such treatment has taken place and the blood glucose value has been rechecked and returned to the normal range. Ultimately, each person with diabetes becomes responsible for all aspects of routine care, and it is important for school staff to facilitate a student in reaching this goal. Regardless of a student's ability to provide self-care, help will always be needed in the event of a diabetes emergency.

#### **Key Points**

- Diabetes care at school should be provided in accordance with the regimen prescribed in the student's DMMP.
- Parents/guardians, the school, the health care provider, and the student all have a role and responsibilities in the provision of diabetes care at school.
- Regardless of a student's ability to provide self-care, adult supervision will be required in the event of a diabetes emergency.
- The ADA has a wealth of comprehensive resources to aid in the training of school employees in the provision of diabetes care to students (www.diabetes.org/safeatschool).

# DIABETES MANAGEMENT AT SCHOOL: SPECIAL CONSIDERATIONS

#### Self-management

Many students can self-manage their diabetes, whereas others need some supervision. Other students need to have diabetes care provided by a school nurse and/or a trained staff member. All students, even those who can independently manage their diabetes, will need assistance in the event of a diabetes emergency.

It is best to monitor blood glucose levels according to plan and respond to the results as quickly and conveniently as possible. A delay in monitoring and treatment could result in a diabetes emergency and contribute to short-term diabetes-related complications, so prompt action is paramount. This also minimizes educational problems caused by missing instruction in the classroom as a result of a delayed treatment.

#### Insulin/Medication Administration

Students with type 1 diabetes and some students with type 2 diabetes need insulin at specified times at school with additional doses to cover hyperglycemia when indicated. The school nurse and trained school staff should be trained on using the student's insulin delivery system (e.g., syringe, insulin pen, or insulin "pump").

# Recognition and Treatment of Hypoglycemia and Hyperglycemia

The school nurse and school staff should be made aware of the symptoms and

signs of hypoglycemia and hyperglycemia and be trained to provide prompt treatment including the administration of glucagon to treat severe hypoglycemia and insulin to treat hyperglycemia.

#### **Nutrition and Physical Activity**

The general nutritional needs of students with diabetes should not differ from the needs of other students. However, there may be differences in the timing, amount and nutrient content of the food, and attention given to ensure carbohydrates are carefully matched to balance insulin action. The school needs to provide the carbohydrate content and nutritional information for school meal menus in advance. Students with diabetes should fully participate in physical education classes and team/individual sports. Students may need to adjust their insulin and food intake during extra physical activity, and a fast-acting source of carbohydrate should be readily available to treat hypoglycemia.

#### Field Trips and Extracurricular Activities

Students with diabetes should be able to participate in field trips and extracurricular activities such as before-school breakfast programs, intramural sports, after-school clubs, detention, and school dances where they will have access to their supplies and the school nurse or trained school staff who can provide diabetes care. Parental attendance cannot be required for the student's participation.

#### Attendance/Absenteeism

Children with diabetes should attend school regularly. It is important that absences happen only when they are medically necessary such as illness or medical appointments. Efforts should be made to schedule appointments to minimize class absences. When absences occur, there should not be unfair consequences for missing class time.

#### Academics and Standardized Testing

Standardized testing and licensing agencies are prohibited from discriminating against otherwise qualified individuals with disabilities under the Americans with Disabilities Act. This includes students with diabetes. Agencies must provide reasonable modifications to such individuals. Applicants taking a variety of scholastic exams (e.g., SAT, ACT, etc.) may request reasonable modifications in the administration of these exams,

including access to self-monitoring equipment, medications, and food.

#### **Key Points**

- Independent and mature students should be permitted to self-manage their diabetes anywhere, anytime and to be able to carry their supplies, medication, and equipment.
- Insulin may be administered by selfmanaging students, a school nurse, or trained school staff using the student's recommended insulin delivery device. The school nurse and trained school staff should be knowledgeable about the symptoms of hypoglycemia and hyperglycemia and be prepared to treat including the administration of glucagon.
- All students, even those who can independently manage their diabetes, will need assistance in the event of a diabetes emergency.
- Carbohydrate and nutrition information for school meals should be provided to the family in advance.
- Students should be permitted to participate in all school-sponsored activities with the school nurse or other trained school staff available to provide diabetes care.
- Students with diabetes should not be penalized for absences related to diabetes.
- · Reasonable modifications by testing agencies should be provided to students with diabetes for standardized tests.

#### **OTHER SETTINGS**

#### **Preschool Setting**

Young children with diabetes have unique needs and require a carefully thought-out, proactive diabetes care plan. Federal laws and some state laws provide protections for the rights of the young child in the preschool setting. ADA's position statement on child care "Care of Young Children With Diabetes in the Child Care Setting" (8) should be reviewed for specific recommendations for children aged <5 years in the child care setting.

#### **Postsecondary Setting**

Students with diabetes are protected under Section 504 and the Americans with Disabilities Act. Students may request reasonable modifications from the institution's office of disability. A written accommodation plan or letters of accommodation may be developed to give professors notice that certain modifications should be provided. ADA's "Going to College With Diabetes: A Self-advocacy Guide for Students" (35) should be reviewed for specific recommendations for postsecondary students with diabetes.

#### **Key Points**

· Reasonable modifications under federal and state laws should be made to students in preschool and postsecondary settings.

#### **SUMMARY**

Diabetes is a common chronic disease in school-aged children. Short- and long-term diabetes-related complications can be delayed or prevented with proper management. Diabetes must be managed 24 h a day, 7 days a week, including the many hours spent at school. To keep students with diabetes safe at school, guarantee long-term health, prevent complications, and ensure full participation in all school activities, proper monitoring of and responding to blood glucose levels must be attended to throughout the school day and during all school-sponsored activities. Coordination of care among the family, school, and diabetes health care provider is critical. With proper planning and the education and training of school staff, children and youth with diabetes can fully and safely participate in school.

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User Name: Katie Hathaway

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### Document (1)

1. American Nurses Assn. v. Torlakson, 57 Cal. 4th 570

Client/Matter: -None-

Search Terms: name(american nurse association) and court(California Supreme Court)

Search Type: Terms and Connectors

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**Content Type** Narrowed by

Cases Timeline: Aug 01, 2013 to Aug 30, 2013; Sources: All

States; Cases

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## American Nurses Assn. v. Torlakson

Supreme Court of California
August 12, 2013, Filed
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#### Reporter

57 Cal. 4th 570 \*; 304 P.3d 1038 \*\*; 160 Cal. Rptr. 3d 370 \*\*\*; 2013 Cal. LEXIS 6649 \*\*\*\*; 2013 WL 4046566

<u>AMERICAN NURSES ASSOCIATION</u> et al., Plaintiffs and Respondents, v. TOM TORLAKSON, as Superintendent, etc., et al., Defendants and Appellants; AMERICAN DIABETES ASSOCIATION, Intervener and Appellant.

**Subsequent History:** Reported at <u>American Nurses</u> <u>Assn. v. Torlakson, 2013 Cal. LEXIS 8393 (Cal., Aug.</u> 12, 2013)

**Prior History:** [\*\*\*\*1] Superior Court of Sacramento County, No. 07AS04631, Lloyd G. Connelly, Judge. Court of Appeal, Third Appellate District, No. C061150.

American Nurses Assn. v. O'Connell, 185 Cal. App. 4th 393, 110 Cal. Rptr. 3d 305, 2010 Cal. App. LEXIS 842 (Cal. App. 3d Dist., June 8, 2010)

#### **Core Terms**

medication, insulin, Nurses, unlicensed, school personnel, Advisory, licensed, diabetes, pupil, medical-orders, regulations, administered, statutes, orders, trained, personnel, healthcare provider, schools, implementing regulations, italics, school nurse, state law, designated, prescription medication, recommendations, injection, permits, registered nurse, public school, carrying

## Case Summary

#### **Procedural Posture**

The trial court declared a legal advisory issued by appellant California Department of Education invalid and issued a writ of mandate ordering the Department not to enforce the advisory to the extent it permitted unlicensed school personnel to administer insulin to

diabetic students. The California Court of Appeal, Third Appellate District, affirmed the judgment and writ of mandate. Appellant diabetes association petitioned for review.

#### Overview

Finding no merit in the arguments to the contrary, the Supreme Court held that state law (specifically Ed. Code, § 49423, along with its implementing regulations) permits trained, unlicensed school personnel to administer prescription medications, including insulin, in accordance with written statements of individual students' treating physicians, with parental consent. Persons who act under this authority do not violate the California Nursing Practices Act, Bus. & Prof. Code, § 2700 et seq. State law reflects the practical reality that most insulin administered outside of hospitals and other clinical settings is in fact administered by laypersons. Because schools may administer prescription medications only in accordance with physicians' written statements, state law in effect delegates to each student's physician the decision whether insulin may safely and appropriately be administered by unlicensed school personnel or instead whether a particular student's medical needs can be met only by a licensed health care provider. State law presents no categorical obstacle to the use of unlicensed personnel for this purpose.

#### **Outcome**

The appellate court's judgment was reversed, and the case was remanded for further proceedings.

#### LexisNexis® Headnotes

Civil Procedure > Appeals > Standards of Review > De Novo Review

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57 Cal. 4th 570, \*570; 304 P.3d 1038, \*\*1038; 160 Cal. Rptr. 3d 370, \*\*\*370; 2013 Cal. LEXIS 6649, \*\*\*\*1

Civil Procedure > Appeals > Standards of Review > Questions of Fact & Law

## **HN1**[基] Standards of Review, De Novo Review

Questions of law are subject to de novo review.

Education Law > Faculty & Staff > General Overview

Education Law > Students > Counseling & Health Services > Health Related Services

## HN2 Law, Faculty & Staff

See Ed. Code, § 49423, subd. (a).

Education Law > Faculty & Staff > General Overview

Education Law > Students > Counseling & Health Services > Health Related Services

## **HN3**[基] Education Law, Faculty & Staff

See Ed. Code, § 49423, subd. (b).

Education Law > Faculty & Staff > General Overview

Education Law > Students > Counseling & Health Services > Health Related Services

## HN4[♣] Education Law, Faculty & Staff

Ed. Code, § 49423, which governs the administration of prescribed medication for pupils by a school nurse or other designated school personnel, applies notwithstanding Ed. Code, § 49422, which provides more generally that only licensed health care providers may be permitted to supervise the health and physical development of pupils.

Education Law > Faculty & Staff > General Overview

Education Law > Students > Counseling & Health Services > Health Related Services

## HN5[₺] Education Law, Faculty & Staff

See Cal. Code Regs., tit. 5, § 604.

Education Law > Faculty & Staff > General Overview

Education Law > Students > Counseling & Health Services > Health Related Services

## HN6[≰] Education Law, Faculty & Staff

Cal. Code Regs., tit. 5, § 601, subd. (e), defines "other designated school personnel" who may administer medication to pupils as including any individual employed by the local education agency who: (1) has consented to administer the medication to the pupil or otherwise assist the pupil in the administration of the medication; and (2) may legally administer the medication to the pupil or otherwise assist the pupil in the administration of the medication.

Education Law > Faculty & Staff > General Overview

Education Law > Students > Counseling & Health Services > Health Related Services

## <u>HN7</u>[基] Education Law, Faculty & Staff

<u>Ed. Code, § 49423</u>, and its implementing regulations plainly establish that unlicensed school personnel may administer prescription medications to pupils.

Education Law > Faculty & Staff > General Overview

Education Law > Students > Counseling & Health Services > Health Related Services

## HN8 ≥ Education Law, Faculty & Staff

In permitting school personnel other than licensed health care providers to administer medication, <u>Cal. Code Regs., tit. 5, § 601</u> & 604, qualify that permission with language deferring to other laws governing the subject. Specifically, § 604, <u>subd.</u> (a), provides that other designated school personnel may administer medication to pupils as allowed by law. Similarly, § 601,

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 $\underline{subd.}$  (e)(2), limits such "other designated school personnel" to those who may legally administer the medication to the pupil.

Education Law > Faculty & Staff > General Overview

Healthcare Law > Business Administration & Organization > Facility & Personnel Licensing > General Overview

Education Law > Students > Counseling & Health Services > Health Related Services

## HN9[♣] Education Law, Faculty & Staff

However broadly the California Nursing Practice Act (NPA), <u>Bus. & Prof. Code</u>, § 2700 et seq., may define the practice of nursing, and whatever the NPA may correlatively prohibit as unauthorized practice, the NPA expressly exempts from that prohibition the performance by any person of such duties as required in carrying out medical orders prescribed by a licensed physician. <u>Bus. & Prof. Code</u>, § 2727, <u>subd. (e)</u>. This medical-orders exception is broad enough to cover unlicensed school personnel who act as volunteers for specific students, at their parents' request, to carry out physicians' medical orders in accordance with <u>Ed. Code</u>, § 49423, and its implementing regulations.

Healthcare Law > Business Administration & Organization > Facility & Personnel Licensing > General Overview

# <u>HN10</u>[♣] Business Administration & Organization, Facility & Personnel Licensing

See Bus. & Prof. Code, § 2727, subd. (e).

Education Law > Faculty & Staff > General Overview

Healthcare Law > Business Administration & Organization > Facility & Personnel Licensing > General Overview

Education Law > Students > Counseling & Health Services > Health Related Services

## HN11[♣] Education Law, Faculty & Staff

Unlicensed school personnel acting pursuant to <u>Ed.</u> <u>Code</u>, § 49423, and its implementing regulations perform duties as required in carrying out medical orders. <u>Bus. & Prof. Code</u>, § 2727, subd. (e).

Healthcare Law > Business Administration & Organization > Facility & Personnel Licensing > General Overview

# <u>HN12</u> Business Administration & Organization, Facility & Personnel Licensing

To "assume to practice as a professional, registered, graduate or trained nurse" under <u>Bus. & Prof. Code, § 2727, subd. (e)</u>, means to hold oneself out, explicitly or implicitly, as being a nurse in fact.

Education Law > Faculty & Staff > General Overview

Healthcare Law > Business Administration & Organization > Facility & Personnel Licensing > General Overview

Education Law > Students > Counseling & Health Services > Health Related Services

## HN13[基] Education Law, Faculty & Staff

The medical-orders exception set forth in <u>Bus. & Prof. Code</u>, § 2727, <u>subd. (e)</u>, permits a layperson to carry out a physician's medical orders for a patient, even orders that would otherwise fall within the definition of nursing practice, without thereby violating the rule against unauthorized practice. To fall outside the exception by assuming to practice as a nurse, one must go further by holding oneself out, explicitly or implicitly, to be a nurse in fact. Unlicensed school personnel do not hold themselves out to be nurses simply by volunteering to act on behalf of particular students in accordance with the California Education Code and its implementing regulations.

Administrative Law > Judicial Review > Standards of Review > Deference to Agency Statutory Interpretation

57 Cal. 4th 570, \*570; 304 P.3d 1038, \*\*1038; 160 Cal. Rptr. 3d 370, \*\*\*370; 2013 Cal. LEXIS 6649, \*\*\*\*1

Governments > Legislation > Interpretation

Administrative Law > Judicial Review > Standards of Review > Rule Interpretation

# <u>HN14</u>[♣] Standards of Review, Deference to Agency Statutory Interpretation

An agency interpretation of the meaning and legal effect of a statute is entitled to consideration and respect by the courts; however, unlike quasi-legislative regulations adopted by an agency to which the legislature has confided the power to "make law," and which, if authorized by the enabling legislation, bind the courts as firmly as statutes themselves, the binding power of an agency's interpretation of a statute or regulation is contextual. Its power to persuade is both circumstantial and dependent on the presence or absence of factors that support the merit of the interpretation.

Education Law > Faculty & Staff > General Overview

Healthcare Law > Business Administration & Organization > Facility & Personnel Licensing > General Overview

Education Law > Students > Counseling & Health Services > Health Related Services

## **HN15 Law, Faculty & Staff**

California law permits trained, unlicensed school personnel to administer prescription medications, including insulin, in accordance with written statements of individual students' treating physicians, with parental consent, Ed. Code, §§ 49423, 49423.6; Cal. Code Regs., tit. 5, §§ 600-611. Persons who act under this authority do not violate Bus. & Prof. Code, § 2727, subd. (e), of the California Nursing Practices Act, Bus. & Prof. Code, § 2700 et seq. Because schools may administer prescription medications only in accordance with physicians' written statements, § 49423; tit. 5, § 600, subd. (a), state law in effect delegates to each student's physician the decision whether insulin may safely and appropriately be administered by unlicensed school personnel or instead whether a particular student's medical needs can be met only by a licensed health care provider. State law, however, presents no categorical obstacle to the use of unlicensed personnel for this purpose.

## Headnotes/Syllabus

#### Summary

#### CALIFORNIA OFFICIAL REPORTS SUMMARY

The trial court declared a legal advisory issued by the California Department of Education invalid and issued a writ of mandate ordering the department not to enforce the advisory to the extent it permitted unlicensed school personnel to administer insulin to diabetic students. (Superior Court of Sacramento County, No. 07AS04631, Lloyd G. Connelly, Judge.) The Court of Appeal, Third Dist., No. C061150, affirmed the judgment and writ of mandate.

The Supreme Court reversed the judgment of the Court of Appeal and remanded the case for further proceedings. Finding no merit in the arguments to the contrary, the court held that state law (specifically Ed. Code, § 49423, along with its implementing regulations) permits trained, unlicensed school personnel to administer prescription medications, including insulin, in accordance with written statements of individual students' treating physicians, with parental consent. Persons who act under this authority do not violate the Nursing Practices Act (Bus. & Prof. Code, § 2700 et seq.). State law reflects the practical reality that most insulin administered outside of hospitals and other clinical settings is in fact administered by laypersons. Because schools may administer prescription medications only in accordance with physicians' written statements, state law in effect delegates to each student's physician the decision whether insulin may safely and appropriately be administered by unlicensed school personnel or instead whether a particular student's medical needs can be met only by a licensed health care provider. State law presents no categorical obstacle to the use of unlicensed personnel for this purpose. (Opinion by Werdegar, J., with Kennard, Acting C. J., Baxter, Chin, Corrigan, Liu, JJ., and McGuiness, J.,\* concurring.) [\*571]

#### **Headnotes**

CALIFORNIA OFFICIAL REPORTS HEADNOTES

<sup>\*</sup>Presiding Justice of the Court of Appeal, First Appellate District, Division Three, assigned by the Chief Justice pursuant to article VI, section 6 of the California Constitution.

57 Cal. 4th 570, \*571; 304 P.3d 1038, \*\*1038; 160 Cal. Rptr. 3d 370, \*\*\*370; 2013 Cal. LEXIS 6649, \*\*\*\*1

## <u>CA(1)</u>[基] (1)

Schools § 54—Students—Prescribed Medication—School Personnel.

Ed. Code, § 49423, which governs the administration of prescribed medication for pupils by a school nurse or other designated school personnel, applies notwithstanding Ed. Code, § 49422, which provides more generally that only licensed health care providers may be permitted to supervise the health and physical development of pupils.

## CA(2)[1] (2)

Schools § 54—Students—Prescribed Medication— School Personnel.

<u>Ed. Code, § 49423</u>, and its implementing regulations plainly establish that unlicensed school personnel may administer prescription medications to pupils.

## **CA(3)**[**4**] (3)

Schools § 54—Students—Prescribed Medication—School Personnel.

In permitting school personnel other than licensed health care providers to administer medication, <u>Cal. Code Regs., tit. 5, §§ 601</u> & <u>604</u>, qualify that permission with language deferring to other laws governing the subject. Specifically, <u>§ 604, subd. (a)</u>, provides that other designated school personnel may administer medication to pupils as allowed by law. Similarly, <u>§ 601, subd. (e)(2)</u>, limits such "other designated school personnel" to those who may legally administer the medication to the pupil.

## CA(4)[1] (4)

Healing Arts and Institutions § 4—Nursing— Unauthorized Practice—Medical Orders Exception.

However broadly the Nursing Practice Act (NPA) (<u>Bus.</u> & <u>Prof. Code</u>, § <u>2700 et seq.</u>) may define the practice of nursing, and whatever the NPA may correlatively prohibit as unauthorized practice, the NPA expressly exempts from that prohibition the performance by any person of such duties as required in carrying out medical orders prescribed by a licensed physician (<u>Bus.</u>

& Prof. Code, § 2727, subd. (e)). This medical orders exception is broad enough to cover unlicensed school personnel who act as volunteers for specific students, at their parents' request, to carry out physicians' medical orders in accordance with Ed. Code, § 49423, and its implementing regulations.

## **CA(5)**[**소**] (5)

Schools § 54—Students—Medical Orders Exception— School Personnel.

Unlicensed school personnel acting pursuant to <u>Ed. Code</u>, § 49423, and its implementing regulations perform duties as required in carrying out medical orders pursuant to the medical orders exception of <u>Bus.</u> <u>& Prof. Code</u>, § 2727, subd. (e).

## <u>CA(6)</u>[<u>\*</u>] (6)

Healing Arts and Institutions § 4—Nursing—Assume to Practice as Nurse.

To assume to practice as a professional, registered, graduate or **[\*572]** trained nurse under <u>Bus. & Prof.</u> <u>Code, § 2727, subd. (e)</u>, means to hold oneself out, explicitly or implicitly, as being a nurse in fact.

## <u>CA(7)</u>[基] (7)

Healing Arts and Institutions § 4—Nursing— Unauthorized Practice—Medical Orders Exception— School Personnel.

The medical orders exception set forth in <u>Bus. & Prof. Code.</u> § 2727, <u>subd.</u> (e), permits a layperson to carry out a physician's medical orders for a patient, even orders that would otherwise fall within the definition of nursing practice, without thereby violating the rule against unauthorized practice. To fall outside the exception by assuming to practice as a nurse, one must go further by holding oneself out, explicitly or implicitly, to be a nurse in fact. Unlicensed school personnel do not hold themselves out to be nurses simply by volunteering to act on behalf of particular students in accordance with the Education Code and its implementing regulations.

57 Cal. 4th 570, \*572; 304 P.3d 1038, \*\*1038; 160 Cal. Rptr. 3d 370, \*\*\*370; 2013 Cal. LEXIS 6649, \*\*\*\*1

# Administrative Law § 113—Judicial Review—Agency Interpretation of Statute—Quasi-legislative Regulations.

An agency interpretation of the meaning and legal effect of a statute is entitled to consideration and respect by the courts; however, unlike quasi-legislative regulations adopted by an agency to which the Legislature has confided the power to make law, and which, if authorized by the enabling legislation, bind the courts as firmly as statutes themselves, the binding power of an agency's interpretation of a statute or regulation is contextual. Its power to persuade is both circumstantial and dependent on the presence or absence of factors that support the merit of the interpretation.

## **CA(9)**[ **4**] (9)

# Schools § 54—Students—Prescribed Medication—School Personnel—Insulin.

Finding no merit in the arguments to the contrary, the Supreme Court concluded that California law permits trained, unlicensed school personnel to administer prescription medications. including insulin. accordance with written statements of individual students' treating physicians, with parental consent (Ed. Code, §§ 49423, 49423.6; Cal. Code Regs., tit. 5, §§ 600-611). Persons who act under this authority do not violate Bus. & Prof. Code, § 2727, subd. (e), part of the Nursing Practices Act (Bus. & Prof. Code, § 2700 et seq.). Because schools may administer prescription medications only in accordance with physicians' written statements, state law in effect delegates to each student's physician the decision whether insulin may safely and appropriately be administered by unlicensed school personnel or instead whether a particular student's medical needs can be met only by a licensed health care provider. State law, however, presents no categorical obstacle to the use of unlicensed personnel for this purpose.

[Cal. Forms of Pleading and Practice (2013) ch. 471B, Licensing by Public Agencies, § 471B.12; 2 Witkin & Epstein, Cal. Criminal Law (4th ed. 2012) Crimes Against Public Peace and Welfare, § 409.]

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Nurses, Delaware School Nurses Association, Emergency Nurses Association, Florida Association of School Nurses, Georgia Association of School Nurses, Illinois Association of School Nurses, Illinois Nurses Association, Indiana Association of School Nurses, Iowa School Nurses Organization, Kentucky School Nurses Association, Maine Association of School Nurses, Maryland Association of School Health Nurses. Massachusetts School Nurse Association, Michigan Association of School Nurses, National Association of Pediatric Nurse Practitioners, National Association of State School Nurse Consultants, National Board for Certification of School Nurses. Nebraska School Nurse Association, Nevada State Association of School Nurses, New Hampshire School Nurse Association, New Jersey State School Nurses Association, New Mexico School Nurses Association, New York State Association of School Nurses, Ohio Association of School Nurses, Pennsylvania [\*\*\*\*4] Association of School Nurses and Practitioners, Rhode Island Certified School Nurse Teachers, Rhode Island Institute for Nursing, Rhode Island State Nurses Association, School Nurse Organization of Arizona, School Nurse Organization of Idaho, School Nurse Organization of Minnesota, School Social Work Association of America. South Carolina Association of School Nurses, Tennessee Association of School Nurses. Utah School Nurse Association, Vermont State School Nurses Association, Virginia Association of School Nurses, West Virginia Association of School Nurses, Wisconsin Association of School Nurses and Wyoming School Nurses Association as Amici Curiae on behalf of Plaintiffs and Respondents.

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**Judges:** Opinion by Werdegar, J., with Kennard, Acting C. J., Baxter, Chin, Corrigan, Liu, JJ., and McGuiness,

J.,\* concurring.

Opinion by: Werdegar [\*575]

## **Opinion**

#### [\*\*1040] [\*\*\*373] WERDEGAR, J.—

Public school students with diabetes who cannot selfadminister insulin are normally entitled under federal law to have it administered to them during the schoolday. This case presents a dispute over whom state law permits to administer that insulin. The dispute arises against the background of a long-standing shortage of school nurses and a class action in federal court alleging the state's schools have failed to ensure diabetic students actually receive legally required health care services. Pursuant to an agreement settling that litigation, the State Department of Education (Department) in 2007 advised local education agencies that trained school personnel who are not licensed health [\*\*\*\*6] care providers may, when no nurse is available, administer insulin pursuant to the medical orders of students' treating physicians. (State Dept. of Education, Legal Advisory on Rights of Students with Diabetes in California's K-12 Public Schools (2007) pt. IV.C <a href="http://www.cde.ca.gov/ls/he/hn/legaladvisory.asp">http://www.cde.ca.gov/ls/he/hn/legaladvisory.asp</a> [as of Aug. 12, 2013] (2007 Legal Advisory).) In the case now before us, the American Nurses Association and other trade organizations representing registered and school nurses (collectively Nurses) challenge the Department's advice as condoning the unauthorized practice of nursing. The American Diabetes Association (Association), which is a party to the federal settlement agreement, defends the Department's advice as intervener.

In fact, California law expressly permits trained, unlicensed school personnel to administer prescription medications such as insulin in accordance with the written statements of a student's treating physician and parents (*Ed. Code, §§ 49423, 49423.6*; *Cal. Code Regs., tit. 5, §§ 600, 604, subd. (b)*) and expressly exempts persons who thus carry out physicians' medical orders from laws prohibiting the unauthorized practice of nursing (*Bus. & Prof. Code, § 2727, subd. (e)*). [\*\*\*\*7] Through these provisions, state law in effect

\*Presiding Justice of the Court of Appeal, First Appellate District, Division Three, assigned by the Chief Justice pursuant to *article VI*, *section 6 of the California Constitution*.

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leaves to each student's physician, with parental consent, the question whether insulin may safely and appropriately be administered by unlicensed school personnel, and reflects the practical reality that most insulin administered outside of hospitals and other [\*\*\*374] clinical settings is in fact administered by laypersons. The Nurses' arguments to the contrary lack merit.

#### I. BACKGROUND

The question whether California law permits unlicensed school personnel to administer medications is, like all <a href="https://www.energy.com/html">https://www.energy.com/html</a> questions of law, subject to de novo review. (See <a href="https://www.energy.com/html">Bruns v. E-Commerce Exchange, Inc. (2011) 51</a> <a href="https://www.energy.com/cal.4th">Cal.4th 717, 724 [122 Cal. Rptr. 3d 331, 248 P.3d 1185]</a>.) We thus draw freely from the undisputed evidence in setting out the facts of the case before us. [\*576]

Diabetes is a chronic, incurable disease that prevents the human body from properly using food to produce energy. Insulin, a hormone produced in the pancreas, transports glucose (a sugar derived from food) through the bloodstream to the cells. In a person with diabetes, the body either does not produce insulin, or enough insulin (type 1 diabetes), or cannot use insulin properly (type 2 diabetes). All persons with type 1 diabetes and some with type [\*\*\*\*8] 2 must take insulin to avoid serious short- and long-term health problems. (See generally U.S. Dept. of Health & Human Services, Helping the Student with Diabetes Succeed: A Guide for School Personnel (2010)<a href="http://www.ndep.nih.gov/media/youth">http://www.ndep.nih.gov/media/youth</a> schoolguide.pdf > [as of Aug. 12, 2013] (DHHS Guide).) State law requires that nurses administer all medications, including insulin, in hospitals and other licensed health care facilities. (Bus. & Prof. Code, § 2725.3.) Outside of such facilities, however, insulin is normally administered by laypersons according to a physician's directions, most often by the diabetic persons themselves or by friends or family members.

Public school students with diabetes who cannot self-administer insulin are normally entitled to have it administered to them at no cost. This is a result of section 504 of the Rehabilitation Act of 1973 (29 U.S.C. § 794) (Section 504), title II of the Americans with Disabilities Act of 1990 (42 U.S.C. § 12131 et seq.), and the Individuals with Disabilities Education Act (20 U.S.C. § 1400 et seq.) (IDEA). (See 28 C.F.R. § 35.104 (2013); 34 C.F.R. § 300.8(c)(9)(i) (2013) [defining diabetes as a

disability].) Public schools must offer [\*\*\*\*9] to students covered by these laws a free and appropriate public education that includes related aids and services, such as medical services, designed to meet their individual educational needs. (See 20 U.S.C. § 1400(d)(1)(A); 34 <u>C.F.R.</u> § 104.33(a), (b)(1) (2013).) Under these laws, diabetic students pay for insulin, supplies and equipment but not the cost of administering insulin. (See 34 C.F.R. § 104.33(c)(1) (2013) [\*\*1041] ["the provision of a free education is the provision of educational and related services without cost to the handicapped person or to his or her parents or guardian ..."]; Cedar Rapids Community School Dist. v. Garret F. (1999) 526 U.S. 66, 79 [143 L. Ed. 2d 154, 119 S. Ct. 9927 [school district must pay for required services].) A school's obligations to a particular diabetic student are normally set out in a "Section 504 plan" or an "individualized education program" (IEP).

Approximately one in 400 school-age children nationwide has diabetes, including about 14,000 in California. The goal of diabetes management for children is to avoid both hyperglycemia (high blood glucose) and hypoglycemia (low blood glucose) by tightly maintaining blood-glucose levels within target ranges determined by their physicians, through frequent [\*\*\*\*10] monitoring and multiple daily insulin injections. (DHHS Guide, p. 15.) Accordingly, diabetic students who depend on insulin injections typically need them during the [\*577] schoolday, both at regularly scheduled times and unpredictably to correct for fluctuations [\*\*\*375] in blood glucose. The need for insulin can arise anytime and anywhere-in the classroom, on field trips or during school-sponsored activities. To serve this and other student health needs, California has about 2,800 school nurses, averaging one for every 2,200 of the state's approximately 6 million public school students. While 5 percent of schools have a full-time school nurse, 69 percent have only a parttime nurse, and 26 percent have no nurse at all. Although some schools allow unlicensed school personnel to administer insulin, others do not. Some of those that do not appear to have taken the position, possibly in reliance on 2005 and 2006 advisory statements by the Department (see post, at p. 588 et seq.), that the Nursing Practice Act (Bus. & Prof. Code, § 2700 et seq.) permits only licensed health care providers to administer insulin in schools. Moreover, some nurses have refused to train unlicensed school personnel to administer [\*\*\*\*11] insulin out of concern for possible disciplinary action by the Board of Registered Nursing. As a result, diabetic students have encountered difficulty in receiving insulin during the

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schoolday.

In October 2005, the parents of four diabetic students in California public schools, together with the Association, filed a class action in federal court alleging that schools in the Fremont Unified School District and the San Ramon Valley Unified School District had failed to meet their obligations to diabetic students under federal law. (K.C. v. O'Connell (N.D.Cal., No. C-05-4077MMC).) The defendants included the Department, the State Superintendent of Public Instruction (Superintendent), the members of the State Board of Education (Board), and officials of the two named school districts. The plaintiffs alleged the districts' schools had refused to prepare Section 504 plans for diabetic students, refused to include provisions for diabetes care in students' IEPs, refused to permit unlicensed school personnel to administer insulin when no nurse was available, and improperly required that parents or parental designees come to school to administer insulin. Because of these asserted violations of [\*\*\*\*12] federal law, plaintiffs further alleged, some parents were required to forego employment and some students had to adopt insulin regimens that entailed less frequent injections, less effective control of blood-glucose levels, and greater risks to their health.

In July 2007, the plaintiffs in the federal litigation entered into a settlement agreement with the Department, the Superintendent and the Board. The agreement required the Department, among other things, to fulfill its legal obligations to monitor local education agencies' compliance with <u>Section 504</u> and the IDEA and to resolve complaints of noncompliance. In addition, and more importantly for present purposes, the Department agreed to issue the 2007 Legal Advisory (see *ante*, at p. 575) summarizing the rights of diabetic students under federal and state law. The Department issued that document in August 2007, and the federal court dismissed the action.

#### [\*578]

In the 2007 Legal Advisory, as relevant here, the Department articulates eight categories of persons authorized to administer insulin to students in the state's public [\*\*1042] schools. The Department describes the first seven categories as specifically authorized in statutory exceptions to the [\*\*\*\*13] Nursing Practice Act (Bus. & Prof. Code, §§ 2725, subd. (b)(2), 2727, subd. (d)) and in a regulation concerning the administration of medication adopted by the Board (Cal. Code Regs., tit. 5, § 604). Briefly, those seven categories include: (1) students who are able to self-administer, (2) nurses and

physicians employed by local [\*\*\*376] education agencies, (3) other school employees who are appropriately licensed health care providers, (4) licensed nurses working pursuant to contracts with schools, (5) parents and guardians, (6) persons designated by parents or guardians who are volunteers but not school employees, and (7) trained, unlicensed school employees acting in emergencies. (2007 Legal Advisory, pt. IV.A.)

The 2007 Legal Advisory also recognizes that some students cannot self-administer insulin, that licensed health care providers are not always available when needed, and that federal law does not permit schools to impose the cost of administering insulin on parents. On that basis, the Department concludes as follows: "When federal and state laws are reconciled, it is clear that it is unlawful for [a local education agency] to have a general practice or policy that asserts that it need not [\*\*\*\*14] comply with the IDEA or Section 504 rights of a student to have insulin administered at school simply because a licensed professional is unavailable. In such situations, federal rights take precedence over strict adherence to state law so that the educational and health needs of the student protected by the Section 504 Plan or IEP are met." (2007 Legal Advisory, pt. IV.C.) So concluding, the Department adds an eighth category of authorized persons, permitting insulin to be administered by a "voluntary school employee who is unlicensed but who has been adequately trained to administer insulin pursuant to the student's treating physician's orders as required by the Section 504 Plan or the IEP." (2007 Legal Advisory, Checklist.) The validity of the 2007 Legal Advisory's "category 8" is the crux of the present dispute.

Two months after the Department issued the 2007 Legal Advisory, the Nurses challenged that document by filing the present action in the superior court seeking declaratory relief and a writ of mandate. The Association responded with a complaint in intervention asking the court to dismiss the Nurses' action. Ultimately the court entered judgment for the Nurses. Accepting their [\*\*\*\*15] argument that state law does not authorize unlicensed school personnel to administer insulin, the court declared the 2007 Legal Advisory invalid to that extent and directed the issuance of a writ of mandate ordering the Superintendent and the Department not to enforce it. The court also declared the same portion of the 2007 Legal Advisory invalid as a regulation adopted in violation of the Administrative Procedure Act (APA) (Gov. Code, [\*579] § 11340 et seq.). Finally, the court rejected the Association's argument that state law, if 57 Cal. 4th 570, \*579; 304 P.3d 1038, \*\*1042; 160 Cal. Rptr. 3d 370, \*\*\*376; 2013 Cal. LEXIS 6649, \*\*\*\*15

interpreted as forbidding unlicensed personnel to administer insulin, is preempted by <u>Section 504</u> and the IDEA.

The Association appealed. The appeal automatically stayed the superior court's decision, leaving the 2007 Legal Advisory provisionally in effect pending the final outcome of these proceedings. (*Code Civ. Proc., § 916, subd. (a)*.) The Court of Appeal affirmed the judgment and writ of mandate without reaching the APA issue. We granted the Association's petition for review. The Superintendent and District, who did not petition for review, support the Association's position as amici curiae.

#### II. DISCUSSION

The main question before us is whether California law [\*\*\*\*16] permits unlicensed school personnel to administer insulin. Our affirmative answer to that question leaves no need to decide whether federal law would preempt a contrary rule of state law or whether the Department violated the APA in promulgating the 2007 Legal Advisory.

A. California Law.

CA(1)[1] (1) To determine whether unlicensed school personnel may administer prescription medications such as insulin, we first consult the body of law that expressly purports to answer the question: Education Code section 49423 [\*\*1043] and its implementing regulations. [\*\*\*378] (All further undesignated citations to statutes are to this code.) The statute declares the basic law: HN2[1] "[A]ny pupil who is required to take, during the regular schoolday, medication prescribed for him or her by a physician and surgeon ... may be assisted by the school nurse or other designated school personnel ... ." (§ 49423, subd. (a), italics added.) The same statute ensures that medications are administered only in accordance with medical orders and parental consent: HN3[1] "In order for a pupil to be assisted by a school nurse or other designated school personnel pursuant to subdivision (a), the school district shall obtain both a written statement from [\*\*\*\*17] the physician ... detailing the name of the medication, method, amount, and time schedules by which the medication is to be taken and a written statement from the parent, foster parent, or guardian of the pupil indicating the desire that the school district assist the pupil in the matters set forth in the statement of the physician ... ." (Id., subd. (b), italics added.) HN4 Section 49423 expressly applies

"[n]otwithstanding <u>Section 49422</u>" (<u>id., subd. (a)</u>), which provides more generally that only licensed health care providers may be "permitted to supervise the health and physical development of pupils" (§ 49422, subd. (a)).

In adopting <u>section 49423</u>, the Legislature repealed and reenacted former section 11753.1. (Stats. 1968, ch. 681, § 1, p. 1378, repealed and reenacted as <u>[\*580]</u> § <u>49423</u> by Stats. 1976, ch. 1010, § 2, pp. 2384, 3615.) The Legislature's reason for authorizing school personnel to administer medications, according to the original statute's legislative history, was to avoid requiring children "to leave school during the day for necessary medication" or compelling their parents "to pay extra sums for a school visit by the physician." (Assem. Education Com., Analysis of Assem. Bill No. 1066 (1968 Reg. Sess.) [\*\*\*\*18] p. 1.)

Section 49423, like its statutory predecessor, did not require implementing regulations and was thus selfexecuting. In the ensuing decades, however, some schools refused to administer prescribed medication to students. Noting this, the Superintendent in a 1997 letter to school superintendents reminded local school administrators that federal law permitted students to receive medication during the schoolday, and that medication could properly be administered unlicensed "personnel who have been appropriately trained by a credentialed school nurse, public health nurse, or physician." (Superintendent Eastin, letter to superintendents of schools, Sept. 5, 1997, p. 2.) Three years later, the same problem came to the attention of the Legislature. A Senate floor analysis, recognizing that "federal case law requires districts to accept responsibility to administer necessary medications ...," reported complaints that "some districts 'have required parents to sign illegitimate blanket waivers that sign away their children's right to medical treatment at school as a condition of enrollment or attendance. In these instances, parents have been forced to take time off work to go to school and [\*\*\*\*19] deliver the medications." (Sen. Rules Com., Off. of Sen. Floor Analyses, Unfinished Business Analysis of Sen. Bill No. 1549 (1999-2000 Reg. Sess.) as amended Aug. 14, 2000, p. 3.) To provide additional clarity, the Legislature directed the Department to develop and recommend, and the Board to adopt, regulations "regarding the administration of medication in the public schools pursuant to Section 49423." (§ 49423.6, subd. (a), added by Stats. 2000, ch. 281, § 2, p. 2477.)

Obeying the Legislature's command, the Board in 2003 adopted sections 600 to 611 of title 5 of the California

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Code of Regulations. (All further references to title 5 are to that code.) These regulations expressly declare that unlicensed school personnel may administer medications. Section 604 provides: HN5[1] "(a) A school nurse may administer medication to a pupil or otherwise assist a pupil in the administration of medication as allowed by law and in keeping with applicable standards of professional practice. [¶] (b) Other designated school personnel may administer medication to pupils or otherwise assist pupils in the administration of medication as allowed by law and, if they are licensed health care professionals, in keeping with applicable standards of professional practice [\*\*\*\*20] for their license." (*Tit. 5, § 604, subds. (a), (b),* italics added.) HN6[1] Section 601 defines the "'[o]ther designated school personnel' " who are thus authorized to act as "includ[ing] any individual employed by the local education agency who: [¶] (1) Has consented to [\*581] administer the medication [\*\*1044] to the pupil or otherwise assist the pupil in the administration of medication; and [¶] (2) May legally administer the medication to the pupil or otherwise assist the pupil in the administration of the medication." (Id., § 601, subd. (e), italics added.) Other sections of title 5 provide for such related matters as medication logs and records, the contents of the physicians' and parents' required written statements, and the delivery, storage and disposal of medications. (Id., §§ 601–609.)

<u>CA(2)</u>[↑] (2) Thus, <u>HN7</u>[↑] <u>section 49423</u> and its implementing regulations plainly establish, as the Legislature, the Board and the Department intended, that unlicensed school personnel may administer prescription medications. The Nurses do not contend the Board's regulations are invalid, but they do offer a variety of arguments for interpreting them other than according to their plain meaning. None is persuasive.

#### 1. "[A]s [\*\*\*\*21] allowed by law."

thns (a) (a) In permitting school personnel other than licensed health care providers to administer medication, sections 601 and 604 of title 5 qualify that permission with language deferring to other laws governing the subject. Specifically, section 604 provides that "[o]ther designated school personnel may administer medication to pupils ... as allowed by law." (Id., subd. (b), italics added.) Similarly, section 601 limits such "[o]ther designated school personnel" to those who "[m]ay legally administer the medication to the pupil ... ." (Id., subd. (e)(2), italics added.) The Nurses contend the italicized language means that only those school personnel who are licensed health care

providers, such as registered nurses, may administer medications, and that unlicensed personnel may assist but not actually administer medications. By way of illustration, the Nurses assert that unlicensed school personnel "are permitted to open a bottle of cough syrup and pour the prescribed dose but cannot pour it down the student's throat," or they may monitor a diabetic student's glucose levels and determine the correct dosage of insulin but may not administer the drug by giving the injection [\*\*\*\*22] or pushing the button on an insulin pump.

The Nurses have misinterpreted the regulations. Before explaining that conclusion, however, and in order to clarify the scope of our holding, we note that one significant premise of the Nurses' argument is correct: There is no reason to believe the Legislature intended to delegate to the Board, a state educational agency charged with governing the public schools (see §§ 33000, 33031), any authority to override statutes in which the Legislature has required specific licensure before a person may perform a health care function. We assume the Board shares this understanding. In section 610 of title 5, [\*\*\*379] the Board explains that "[n]othing in this article may be interpreted [\*582] as ... affecting in any way: [¶] (a) The statutes, regulations, or standards of practice governing any health care professional licensed by the State of California in the carrying out of activities authorized by the license ...." Viewed in this light, the language in the Board's regulations that qualifies the authority of unlicensed school personnel to administer medications—"as allowed by law" (tit. 5, § 604, subd. (a); see id., § 601, subd. (e)(2))—is reasonably [\*\*\*\*23] and appropriately interpreted as reflecting the Board's deference to laws articulating policy choices that lie beyond the scope of its delegated authority over the state's public schools.

This does not mean, however, that only licensed health professionals may administer prescription medications in public schools. It means, rather, only that the Board's regulations do not authorize unlicensed school personnel to administer such medications in violation of other applicable laws or regulations. To illustrate, only licensed health care providers may administer controlled substances. (See Health & Saf. Code, § 11154, subd. (a).) Also, the Legislature has mandated specific training before unlicensed school personnel may administer three specially regulated emergency medications to students. (See §§ 49414 [epinephrine auto-injectors for anaphylaxis], 49414.5 [glucagon for severe hypoglycemia], 49414.7 [antiseizure medication for epilepsy].) A school 57 Cal. 4th 570, \*582; 304 P.3d 1038, \*\*1044; 160 Cal. Rptr. 3d 370, \*\*\*379; 2013 Cal. LEXIS 6649, \*\*\*\*23

employee without the licensure or [\*\*1045] training required by statute for such medications would not be "allowed by law" (tit. 5, § 604, subd. (a)) to administer them and, thus, not permitted to do so solely by force of the Board's regulations. [\*\*\*\*24] Compliance with those other laws would also be necessary.

In contrast, no such law prohibits unlicensed persons from administering prescription medications generally, or insulin in particular, in carrying out the medical orders of licensed physicians. The Nurses attempt to find such a rule in the Nursing Practice Act (NPA) (Bus. & Prof. Code, § 2700 et seq.), which defines the practice of nursing to include a list of patient care functions including "the administration of medications" (id., § 2725, subd. (b)(2)), and prohibits the unauthorized practice of nursing (id., § 2732). In opposition, the Association contends the listed functions fall within the definition of nursing practice only under circumstances where they "require a substantial amount of scientific knowledge or technical skill." (id., § 2725, subd. (b) ["The practice of nursing within the meaning of this chapter means those functions, including basic health care, that help people cope with difficulties in daily living that are associated with their actual or potential health or illness problems or the treatment thereof, and that require a substantial amount of scientific knowledge or technical skill, including all of the [\*\*\*\*25] following ...." (italics added)].) The routine administration of insulin outside of hospitals and clinical settings, the Association observes, does not require substantial [\*583] scientific knowledge or technical skill and is, in fact, typically accomplished by the patients themselves, including some children, or by friends and family members.

CA(4)[1] (4) We need not speak to the definition of nursing practice in order to resolve this case. HN9[1] However broadly the NPA may define the practice of nursing, and whatever the NPA may correlatively prohibit as unauthorized practice, the NPA expressly exempts from that prohibition "[t]he performance by any person of such duties as required in ... carrying out medical orders prescribed by a licensed physician ... ." (Bus. & Prof. Code, § 2727, subd. (e).) This medical-orders exception, as we shall explain, is broad enough to cover unlicensed school personnel who act as [\*\*\*380] volunteers for specific students, at their parents' request, to carry out physicians' medical orders in accordance with section 49423 and its implementing regulations.

2. The Medical-orders Exception.

CA(5)[\*] (5) The medical-orders exception provides in full as follows: HN10 1 "This chapter (the NPA) does not prohibit: [\*\*\*\*26] [¶] ... [¶] (e) The performance by any person of such duties as required in the physical care of a patient and/or carrying out medical orders prescribed by a licensed physician; provided, such person shall not in any way assume to practice as a professional, registered, graduate or trained nurse." (Bus. & Prof. Code, § 2727, subd. (e), italics added.) The meaning of the first clause and its application to this case are clear: HN11 To Unlicensed school personnel acting pursuant to section 49423 and its implementing regulations "perform[] ... duties as required in ... carrying out medical orders ... ." (Bus. & Prof. Code, § 2727, subd. (e).) What the italicized proviso means is less clear, especially in its use of the word "assume." On this point the legislative history is uninformative, reflecting only that section 2727 was added as part of the original NPA (Stats. 1939, ch. 807, § 2, pp. 2346, 2349), and that the medical-orders exception was added on the Assembly floor for unrecorded reasons (Assem. J. (1939) p. 515).

CA(6) (1) (6) The Nurses argue a person "assume[s] to practice as a ... registered ... nurse" (Bus. & Prof. Code, § 2727, subd. (e)) simply by performing any health care function that [\*\*\*\*27] falls within the NPA's definition of nursing practice (id., § 2725, subd. (b)). But this cannot be what the proviso means, as it would vitiate the medical-orders exception. A person who carries out a physician's medical orders with respect to a patient does not need an exception from the laws prohibiting unauthorized practice unless his or her conduct would otherwise violate those laws. To adopt the Nurses' interpretation would thus render the exemption entirely meaningless-a result we would hesitate to accept "unless absolutely necessary." (E.g., People v. Arias (2008) 45 Cal.4th 169, 180 [85 Cal. Rptr. 3d 1, 195 P.3d 103].) But we need [\*584] not accept it. The statute's [\*\*1046] language, broader statutory context and interpretive history all point to a different meaning: HN12 To "assume to practice as a professional, registered, graduate or trained nurse" (Bus. & Prof. Code, § 2727, subd. (e), means to hold oneself [\*\*\*381] out, explicitly or implicitly, as being a nurse in fact.

We begin with the language. To "assume" to do a thing has two possible meanings in the present context. It might mean to "undertake" to do a thing, or "[t]o take [a thing] upon oneself"—in effect simply to do it. (Oxford English Dict. Online (2013) definition II.4.a; [\*\*\*\*28] see Webster's 3d New Internat. Dict. (2002) p. 133,

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definition 2.) Alternatively, to "assume" might mean "[t]o put forth claims or pretensions," to do a thing "in appearance only, ... to pretend, simulate, feign." (Oxford English Dict. Online, *supra*, definition III.8, 9; see Webster's 3d New Internat. Dict., *supra*, at p. 133, definition 4.) Building upon the former definition ("undertake"), the Nurses contend a person "assume[s] to practice as a ... nurse" (*Bus. & Prof. Code*, § 2727, *subd. (e)*) by undertaking to perform—in other words, simply by performing—any of the patient care functions listed in the NPA's definition of nursing (*id.*, § 2725, *subd. (b)(2)*). This interpretation, as noted, cannot be correct as it would leave the medical-orders exception without meaning.

In contrast, the medical-orders exception does have meaning if one "assume[s] to practice as a ... nurse" (Bus. & Prof. Code, § 2727, subd. (e)) by holding oneself out, explicitly or implicitly, as being a nurse in fact. The broader statutory context supports this interpretation. The list of statuses an unlicensed person who carries out medical orders may not "assume"— "professional, registered, graduate [\*\*\*\*29] nurse" (ibid.)—indicates that one may not evade the rule against falsely posing as a registered nurse by substituting a vaguer term such as "professional," "graduate" or "trained." A penal provision enacted by the same Legislature in the same bill as the medical-orders exception similarly declared it "unlawful for any person or persons not licensed as provided in this chapter to impersonate in any manner or pretend to be a professional nurse, or to use the title 'registered nurse,' the letters 'R.N.,' or the words 'graduate nurse,' 'trained nurse,' or any other name, word or symbol in connection with or following his [or her] name so as to lead another or others to believe that he [or she] is a professional nurse." (Id., former § 2796, added by Stats. 1939, ch. 807, § 2, pp. 2346, 2356; see § 2796 [current version, adding "nurse anesthetist" to the list of titles one may not falsely assume].) The order in which the bill's provisions were drafted suggests the Assembly looked to the penal provision, and even borrowed some of its terms, in drafting the floor amendment that added the medical-orders exception. (Compare Assem. Bill No. 620 (1939 Reg. Sess.) § 2, p. 11, as introduced [\*\*\*\*30] Jan. 13, 1939 [adding <u>Bus. & Prof. Code, §</u> 2796], with Assem. J. (1939) p. 515 [floor amend. of Mar. 13, 1939, adding Bus. & Prof. Code, § 2727, subd. (e)].)

#### [\*585]

The broader statutory context provides additional evidence supporting our conclusion. The same section

of the NPA that contains the medical-orders exception (Bus. & Prof. Code, § 2727) also creates a narrower exception covering "[i]ncidental care of the sick by domestic servants or by persons primarily employed as housekeepers as long as they do not practice nursing within the meaning of this chapter" (Id., subd. (b), italics added). Read in the context of the whole statute, the italicized language expresses the thought that domestic servants and housekeepers caring for sick persons may not perform nursing functions, without regard to how they hold themselves out. The Nurses would interpret the medical-orders exception similarly, yet the same Legislature, in the same act and section, chose the different words—"assume to practice as a ... nurse"— (ibid., italics added) to qualify the exception for unlicensed persons who merely carry out medical orders. The inescapable inference is that the Legislature, by using [\*\*\*\*31] different words to define the two exceptions, intended them to have different meanings.

The single prior interpretation of the medical-orders exception is consistent with our conclusion. The Attorney General has described that exception, and the NPA's related penal provisions, as "show[ing] a legislative [\*\*1047] intent to prohibit any person from holding out to the public that [he or] she is specially trained or registered in the nursing profession unless said person is licensed by the state of California in this field." (Registered Nurse, 32 Ops.Cal.Atty.Gen. 159, 160 (1958), referring to <u>Bus. & Prof. Code</u>, §§ 2727, subd. (e) [medical-orders exception; unlicensed person carrying out medical orders may not assume to practice as a nurse], 2795 [unlawful to use any title, sign, card or device to indicate nursing licensure], and <u>2796</u> [unlawful to use the titles "registered," "graduate" or "trained nurse," or the letters "R.N."].) Thus, the Attorney General concluded, an unlicensed person employed by a physician as a "doctor's nurse" was forbidden to use titles confusingly similar to "registered nurse," such as " 'Registered Doctor's [\*\*\*382] Nurse' or the abbreviation 'R.D.N.' or any title, or wear or [\*\*\*\*32] display any pin that would indicate that said person is duly licensed as a registered nurse under the laws of the state of California." (Registered Nurse, supra, at p. 159; cf. Kolnick v. Board of Medical Quality Assurance (1980) 101 Cal. App. 3d 80, 84 [161 Cal. Rptr. 289] [declining to construe the exception].)

CA(7) (7) For all of these reasons, we conclude HN13 (↑) the medical-orders exception does permit a layperson to carry out a physician's medical orders for a patient, even orders that would otherwise fall within the

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definition of nursing practice, without thereby violating the rule against unauthorized practice. To fall outside the exception by "assum[ing] to practice as a ... nurse" (<u>Bus. & Prof. Code, § 2727, subd. (e)</u>), one must go further by holding oneself out, explicitly or implicitly, to be a nurse in fact. This conclusion disposes of the issue, because unlicensed school personnel do not hold themselves out to be **[\*586]** nurses simply by volunteering to act on behalf of particular students in accordance with the Education Code and its implementing regulations.

We thus proceed to consider the Nurses' remaining objections to the conclusion that such personnel may administer medications.

#### 3. Medication-specific Statutes.

In [\*\*\*\*33] statutes enacted between 2001 and 2011, the Legislature imposed additional training and administrative requirements before unlicensed school personnel may administer three specific emergency medications: epinephrine auto-injectors to anaphylaxis (§ 49414, added by Stats. 2001, ch. 458, § 2, p. 4024), glucagon for severe hypoglycemia (§ 49414.5, added by Stats. 2003, ch. 684, § 1, p. 5229, as subsequently amended), and antiseizure medication for epilepsy (§ 49414.7, added by Stats. 2011, ch. 560, § 2). Each of these statutes, while expressing the Legislature's preference that registered nurses administer the subject medications whenever possible, expressly permits trained, unlicensed school personnel to do so when no nurse is available. (See §§ 49414, subd. (f)(1), 49414.5, subd. (a), 49414.7, subds. (a), (b).)

The Nurses contend these statutes would not have been necessary if the NPA's medical-orders exception already, by its own force, permitted unlicensed school personnel to administer medications. "[T]he Legislature," the Nurses observe, "does not engage in idle acts." (Citing California Teachers Assn. v. Governing Bd. of Rialto Unified School Dist. (1997) 14 Cal.4th 627, 634 Cal. Rptr. 2d 671, 927 P.2d 1175].) The [\*\*\*\*34] maxim is valid, but its application is flawed. Having generally authorized unlicensed school personnel to administer medications (§ 49423) and directed the Board to adopt implementing regulations (§ 49423.6), the Legislature nevertheless retained the power to impose additional restrictions on drugs deemed to justify special precautions. Nothing in section 49423 or 49423.6 conditioned the effectiveness of those statutes on further legislation, and nothing in the laterenacted, drug-specific statutes repeals the general

authority granted in the earlier, more general provisions. So understood, none of the relevant statutes represents an idle act. In contrast, to accept the Nurses' argument would entail the implausible conclusion that the Legislature had intended section 49423 and its 1968 statutory predecessor (former § 11753.1; see ante, at pp. 579-580) to lie dormant and ineffective until the Legislature enacted the first drug-specific statute 33 years later. (§ 49414 [concerning epinephrine autoinjectors].) History is to [\*\*1048] the contrary. As we have seen, the 1968 Legislature [\*\*\*383] intended the original statute to be self-executing, and the 2000 Legislature, to force compliance, directed the Board [\*\*\*\*35] to adopt implementing regulations in short order. (See § 49423.6 ["[o]n or before June 15, 2001"]; see also ante, at p. 580.)

#### [\*587]

#### 4. Failed Legislation.

Despite the foregoing evidence to the contrary, amici curiae supporting the Nurses urge us to infer from a variety of failed bills that the Legislature believes further, specific legislation is necessary before unlicensed school personnel may administer insulin. Because section 49423 and its implementing regulations plainly do authorize such personnel to administer prescription medications and were in fact adopted for that purpose, "to undertake the problematic exercise of inferring legislative intent from subsequent, failed legislation seems especially inappropriate ....." (Martin v. Szeto (2004) 32 Cal.4th 445, 451–452 [9 Cal. Rptr. 3d 687, 84 P.3d 374].) In any event, we find nothing in the failed bills' history that supports amici curiae's argument.

Assembly Bill No. 481 (2001-2002 Reg. Sess.) would have required school administrators and other designated, unlicensed personnel to be trained to administer insulin and required them to administer it, in the absence of a school nurse, in accordance with guidelines on diabetes care to be developed by a group of seven state [\*\*\*\*36] and private organizations. The Governor vetoed the bill, explaining his reasons as follows: "Existing law already provides that any pupil who is required to take prescription medication during the regular school day may be assisted by school personnel if a written statement is obtained from a physician and a written request is made by the pupil's parent/guardian. [¶] This bill, while well-intentioned, would create a costly new state reimbursable mandate estimated by the Department of Finance to be potentially tens of millions of dollars. Neither this bill, nor the 2002 Budget Act contains an appropriation for this

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purpose." (Governor's veto message to Assem. on Assem. Bill No. 481 (Sept. 26, 2002) 6 Assem. J. (2001–2002 Reg. Sess.) p. 8873 [in relevant part].)

This history does not show the Legislature in 2002—let alone in 1968 and 1976 when it enacted and reenacted the operative language of section 49423—believed that further, more-specific legislation was required to permit unlicensed school personnel to administer prescription medication. To the contrary, the Legislative Counsel's Digest of the vetoed 2002 bill noted that "[e]xisting law provides that any pupil who [\*\*\*\*37] is required to take ... medication ... may be assisted by the school nurse or other designated school personnel ...," and explained that the bill "would specifically make those provisions applicable to a pupil with diabetes" under guidelines to be developed later. (Legis. Counsel's Dig., Assem. Bill. No. 481 (2001-2002 Reg. Sess.), italics added.) The bill was, thus, analogous to other statutes in which the Legislature has imposed, for particular medications (e.g., epinephrine, glucagon and antiseizure medication), additional restrictions on schools' use of the general authority concerning medications granted in section 49423. The Legislature's unsuccessful attempt to impose comparable restrictions on insulin did not abrogate the existing general authority.

#### [\*588]

Three additional failed bills did not come to a vote. Senate Bill No. 1487 (2007-2008 Reg. Sess.) would have amended section 49414.5, which permits unlicensed school personnel with special training to administer glucagon in emergencies, to administer insulin under similar conditions. (Sen. Bill No. 1487, § 1.) Another bill, [\*\*\*384] Assembly Bill No. 1802 (2009-2010 Reg. Sess.), while expressly authorizing unlicensed personnel to [\*\*\*\*38] administer insulin, would have permitted parents, rather than school administrators, to designate the school employees who would be allowed to administer insulin. (Id., § 2.) Finally, Assembly Bill No. 1430 (2009-2010 Reg. Sess.) would have provided that no one other than licensed health care providers would be allowed to administer any medications in schools, except in emergencies. (Id., § 2.) Because none of these bills came to a vote, and because the Legislature's cursory deliberations on them postdated section 49423's [\*\*1049] enactment by decades, none provides a sound basis for inferring the 1968 and 1976 Legislatures' intents on the question whether section 49423 permits unlicensed personnel to administer insulin.

5. The Department's 2005 and 2006 Advisory Statements.

<u>CA(8)</u>[1] (8) In 2005 and 2006, the Department issued advisory statements recommending that school personnel other than licensed health care providers not administer medications by injection generally (2005) or insulin in particular (2006). (State Dept. of Education, Program Advisory on Medication Administration (May 2005) <a href="http://www.cde.ca.gov/ls/he/hn/documents/medadvisor">http://www.cde.ca.gov/ls/he/hn/documents/medadvisor</a> *y.pdf*> [as of Aug. 12, 2013] (2005 Program Advisory); [\*\*\*\*39] Dept. of State Education, Medication Administration Assistance in California ... Frequently Asked Questions (2006) p. 1 (2006 FAQ).) The Nurses contend we should defer to these recommendations as authoritative interpretations of section 49423 by an agency charged with its enforcement. But the Department's advisory statements are not entitled to the same judicial deference as the binding, quasi-legislative regulations formally adopted by the Board. (Tit. 5, §§ 600–611; see § 49423.6 [regulatory authority].) HN14 1 "An agency interpretation of the meaning and legal effect of a statute is entitled to consideration and respect by the courts; however, unlike quasi-legislative regulations adopted by an agency to which the Legislature has confided the power to 'make law.' and which, if authorized by the enabling legislation, bind this and other courts as firmly as statutes themselves, the binding power of an agency's interpretation of a statute or regulation is contextual: Its power to persuade is both circumstantial and dependent on the presence or absence of factors that support the merit of the interpretation." (Yamaha Corp. of America v. State Bd. of Equalization (1998) 19 Cal.4th 1, 7 [78 Cal. Rptr. 2d 1, 960 P.2d 1031].)

[\*589]

Reviewing the [\*\*\*\*40] 2005 Program Advisory and the 2006 FAQ under these principles, we find they lack persuasive force. Before explaining that conclusion, however, we note those documents do not reflect the Department's current position. In their amicus curiae brief to this court, the Department and the Superintendent maintain that <a href="mailto:section 49423">section 49423</a> and its implementing regulations (<a href="mailto:tit.5">tit.5</a>, <a href="mailto:section 49423">\$\$ 600-611</a>), in combination with the NPA's medical-orders exception (<a href="mailto:Bus.8">Bus. & Prof. Code, § 2727, subd. (e)</a>), do indeed permit unlicensed school personnel to administer insulin. With that clarification, we turn to the documents in question.

In its 2005 Program Advisory, the Department confirmed that unlicensed personnel may administer medications

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generally but "recommend[ed] that ... [¶] ... [¶] ... unlicensed staff member[s] ... not administer medications that must be administered by injection ...." (Id., at p. 7.) The 2005 Program Advisory's recommendations are nonbinding, both because the document so states (id., at p. 1) and as a matter of law (see § 33308.5, subd. (a) ["Program guidelines issued by the [Department] shall be designed to serve as a [\*\*\*385] model or example, and shall not be prescriptive."]; tit. 5, § 611 ["The [Department], with the [\*\*\*\*41] approval of the [Board], may issue and periodically update an advisory providing non-binding guidance on the administration of medication .... The advisory shall be a program guideline under ... section 33308.5 .... "]). The 2005 document offers no discussion or analysis of its recommendation concerning injections and cites no authority that might support it. The document does cite section 49423 and sections 600, 601 and 604 of title 5 (2005 Program Advisory, at p. 6), which, as we have seen, were specifically intended to permit unlicensed personnel to administer medications, and none of which forbids administration by injection. The document also cites statutes describing the specific licensure required of physicians, nurses and other health care providers employed as such in the schools (§§ 44871, 44873–44878), and also section 49422, which provides that only licensed health care providers and certain other persons with relevant credentials "shall be ... employed or permitted to supervise the health and physical development of students .... " (2005 Program Advisory, at p. 20.) As already noted, however, section 49422 cannot mean that only licensed health care providers may [\*\*\*\*42] administer medications in schools because section 49423 expressly applies [\*\*1050] "[n]otwithstanding Section 49422." (§ 49423, subd. (a).)

Unlike the 2005 Program Advisory, which the Department issued with the Board approval required for such documents (see § 33308.5; tit. 5, § 611), the Department apparently issued the 2006 FAQ unilaterally. In that document, the Department flatly asserts that unlicensed school personnel may not administer insulin. (2006 FAQ, at p. 1.) Ignoring its own conclusion just one year earlier that unlicensed personnel may administer medications generally, even if not by injection, the Department in the 2006 FAQ wrote that "[n]o ... California statute" other than sections 49414 (epinephrine auto-injectors) and [\*590] 49414.5 (glucagon) "allows an unlicensed school employee to administer any other medication in California public schools, even if the unlicensed school employee is trained and supervised by a school nurse or other

similarly licensed nurse." (2006 FAQ, at p. 1, italics added.) In attempting to justify this conclusion, the Department inexplicably cited <u>section 49423</u> (2006 FAQ, at p. 2, fn. 2) and omitted any reference to the statute's implementing regulations [\*\*\*\*43] (e.g., <u>tit. 5, § 604, subd. (b)</u> ["Other designated school personnel may administer medication to pupils ...."]).

In its 2006 FAQ, the Department also invoked the NPA as authority for the following assertion: "California law states, with a few clearly specified legal exceptions, that only a licensed nurse or physician may administer medication. In the school setting, these exceptions are situations where: [¶] The student self-administers the medication; [¶] A parent or parent designee, such as a relative or close friend, administers the medication; or [¶] There is a public disaster or epidemic." (2006 FAQ, at p. 1, fns. omitted.) The noted exceptions reflect statutory exceptions to the NPA. (Bus. & Prof. Code, § 2727, subds. (a) [gratuitous nursing by friends or family members], (d) [nursing services in emergencies].) But the document entirely overlooks the medical-orders exception, which expressly permits "any person [to perform] ... such duties as required in ... carrying out medical orders prescribed by a licensed physician ...." (Id., subd. (e).)

Viewing the 2005 Program Advisory and the 2006 FAQ in their full legal context, we conclude the documents' recommendations are not entitled [\*\*\*\*44] to judicial deference to the [\*\*\*386] extent they might be thought to preclude unlicensed school personnel from administering insulin. The 2005 Program Advisory makes no serious effort to reconcile its recommendation concerning injections with the applicable statutes (§§ 49423, 49423.6) and binding regulations (tit. 5, §§ 601-611), and ignores the NPA's medical-orders exception (Bus. & Prof. Code, § 2727, subd. (e)). The 2006 FAQ shares these faults and, in addition, both contradicts the 2005 Program Advisory's correct conclusion that unlicensed personnel may administer medications generally and lacks the Board approval required for program guidelines. (See § 33308.5; tit. 5, § 611.) Under these circumstances, the documents' recommendations lack persuasive force on the question before us, and we thus do not defer to them. (Yamaha Corp. of America v. State Bd. of Equalization, supra, 19 Cal.4th 1, 7.) We recognize, however, that the 2005 Program Advisory constitutes an important source of advice for local education agencies on matters beyond the scope of this case, and we emphasize that we reject that documents' recommendations only to the extent they contradict the views set out in this [\*\*\*\*45] opinion.

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#### [\*591]

#### 6. Conclusion.

CA(9) (9) Finding no merit in the arguments to the contrary, we conclude HN15 California law does permit trained, unlicensed school personnel to administer prescription medications, including insulin, in accordance with written statements of individual students' treating physicians, with parental consent (§§ 49423, 49423.6; tit. 5, §§ 600-611), and that persons who act under this authority do not violate the NPA (see Bus. & Prof. Code, § 2727, subd. (e)). Because schools may administer prescription medications only in accordance with physicians' written statements (§ 49423; tit. 5, § 600, subd. (a)), state law in effect delegates to each student's physician the decision whether insulin may safely and appropriately be administered by unlicensed school personnel or instead whether a particular [\*\*1051] student's medical needs can be met only by a licensed health care provider. State law, however, presents no categorical obstacle to the use of unlicensed personnel for this purpose.

In view of this conclusion, we need not address the Association's contention that federal law would preempt a contrary rule.

#### B. The APA.

The Nurses contend the 2007 Legal Advisory is ineffective on the [\*\*\*\*46] theory the Department should have adopted it as a regulation in compliance with the APA. (*Gov. Code, § 11340 et seq.*) The superior court agreed with the Nurses on this point. The Court of Appeal, ruling for the Nurses on other grounds, did not reach the issue.

We also do not reach the issue, for two reasons: First, the Nurses forfeited the issue in this court by failing to file, in response to the petition for review, an answer raising it. (See <u>Cal. Rules of Court, rule 8.500(a)(2).</u>) While we have the power to address additional issues (id., <u>rule 8.516(b)(1)</u>), the briefs touch upon the APA issue only cursorily, and we have not requested additional briefing (cf. <u>Cal. Rules of Court, rule 8.516(b)(2)</u>).

Second, and more importantly, our holding that California law permits unlicensed school personnel to administer insulin authoritatively resolves the dispute independently of the 2007 Legal Advisory, based on the relevant provisions of the Education Code and its implementing regulations. We therefore need not

determine whether the Department violated the APA in adopting the 2007 Legal Advisory. Our decision leaves the Department free to revise the Legal Advisory to reflect California [\*\*\*387] law [\*\*\*\*47] as we have interpreted it, and leaves the parties and the lower courts free to identify and resolve, if necessary, any issues that may remain concerning APA compliance. [\*592]

#### III. Disposition

The Court of Appeal's judgment is reversed and the case is remanded for further proceedings in accordance with the views set forth herein.

Kennard, Acting C. J., Baxter, J., Chin, J., Corrigan, J., Liu, J., and McGuiness, J.,\* concurred.

**End of Document** 

<sup>\*</sup>Presiding Justice of the Court of Appeal, First Appellate District, Division Three, assigned by the Chief Justice pursuant to article VI, section 6 of the California Constitution.

#### IX. CERTIFICATE OF SERVICE

I hereby certify that on June 28, 2018, I electronically filed the foregoing *AMICI CURIAE* BRIEF FOR AMERICAN ASSOCIATION OF DIABETES EDUCATORS, CHILDREN WITH DIABETES, ENDOCRINE SOCIETY, INTERNATIONAL SOCIETY FOR PEDIATRIC AND ADOLESCENT DIABETES, PEDIATRIC ENDOCRINE SOCIETY AND TYPE 1 DIABETES EXCHANGE with the Clerk of the U.S. Court of Appeals for the Ninth Circuit by using the appellate CM/ECF system. All participants in the case are registered CM/ECF users and service will be accomplished by the appellate CM/ECF system.

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