FINAL STATEMENT OF REASONS

UPDATE OF INITIAL STATEMENT OF REASONS

The proposed regulations provide clarification for implementing Education Code section 49423. Specifically, the regulations help clarify who may administer medications (or provide assistance with administration of medications) to pupils requiring medication during the regular school day, under what conditions such administration of medications (or rendering of assistance with administration of medications) may occur, and other issues, such as delivery, administration documentation, and disposal of medications.

Currently confusion exists regarding the of application of Education Code section 49423, and local education agencies, parents/guardians, and pupils are seeking and would benefit from clarification of the provisions related to the administration of medications (and rendering of assistance with the administration of medications) to pupils during the regular school day.

The State Board adopted regulations regarding the administration of medication (or rendering of assistance with administration of medication) on September 10, 2003, pursuant to Education Code section 49423.6.

SUMMARY AND RESPONSE TO COMMENTS RECEIVED DURING NOTICE PERIOD OF JUNE 20, 2003 THROUGH AUGUST 5, 2003.

General Comments

Comment #1: Lydia Bourne states that the permissiveness of the regulations provides little or no guidance to the local education agency when using "other designated school personnel" to provide assistance. She wonders how unlicensed lay personnel will be trained to provide whatever assistance is necessary. She asks, "Are we to assume there will be no training of these non-medical people when they volunteer to provide assistance to students?" She also asks what will be the determining factors for supervising "other designated school personnel" and who will determine these factors. She closes by saying, "The lack of direction and guidance puts at risk the concept of *in loco parentis* and subsequently there exists a possible threat to student health and safety."

Response: The State Board notes the comments. The proposed regulations provide as much direction as is possible in relation to the underlying statute. To the extent that the comments suggest that the regulations should require training for "non-medical people," such a requirement would constitute a mandate for a higher level of service for which no source of reimbursement exists. Further, nothing in the regulations precludes a local education agency from providing training for individuals who are legally authorized to administer medication or to render assistance in medication administration. In relation to the question of the "determining factors for supervising 'other designated school personnel' and who will determine these factors," other existing statutes and regulations (within the Education Code and other codes) govern who may supervise the delivery of health care services in schools. Consequently, there is no need to readdress this issue in these regulations. To the extent the comments suggest non-binding guidance for these specific areas (training and supervision), the State Board has provided for issuance and periodic updating of an advisory in Section 611. The advisory would be the appropriate place for non-binding guidance that is of a lengthy nature; regulations would not be the appropriate place for lengthy guidance of this type.

Comment 2: Wendy Vaughn states that the Board of Registered Nursing is pursuing legal definitions of "assist" and "administer" as the terms apply to the administration of medication to pupils. She writes, "If the terms are narrowly defined, we expect that this would create some conflict over the roles of licensed medical personnel and other designated school personnel in administering medication to pupils. Is the

Department of Education aware of this issue and its possible effects on the implementation of the Education Code and these regulations? What would the Department of Education recommend in terms of school districts' approach to this issue?"

Response: The State Board is aware of the intention of the Board of Registered Nursing to pursue such definitions and notes the comment. The language in the regulations is clear in stating that in order to administer medication (or assist with medication administration), an individual must be legally capable of so doing. The State Board of Education has no authority to determine the legality of a given individual administering medication (or rendering assistance in the administration of medication). Moreover, the State Board understands that statutes (other than the Education Code) and state agencies (other than itself) do have authority in regard to determining the legality of an individual administering medication (or assisting with the medication administration). The regulatory language clearly reflects those facts. The State Board is unable through regulation to empower an individual in regard to medication administration (or assisting with medication administration) in ways that are contrary to statute or to the authority of other state agencies.

Comment 3: Wendy Vaughn asks why the regulations do not address specific health conditions or different types of prescribed medications.

Response: The State Board notes the comment. There is no statutory authority to single out specific health conditions or different types of prescribed medications. Additionally, creating a point-in-time list of certain health conditions or medications that may need more specialized training, etc., would be ill advised because the list would likely be out-of-date very quickly. Moreover, unless the list was precisely in line with other legal authority, its existence could create a mandate for a higher level of service for which no reimbursement funding is available.

Comment 4: Wendy Vaughn asks how the regulations are to be interpreted in light of school districts' obligations under federal and state law to special education students.

Response: The State Board notes the comment. As stated in section 610, these medication regulations do not alter the content or implementation of a pupil's individualized education program or Section 504 Accommodation Plan that has been prepared in accordance with federal and state laws. Local education agencies' obligations under federal and state law to special education students and to other students with special health care needs who qualify under Section 504 are not changed by these regulations.

Comment 5: Wendy Vaughn states that the regulations create the likelihood of continued confusion and disagreement concerning appropriate roles and procedures for administering medication to students. She asserts that without clear legal guidance to determine the appropriate procedures and roles for school personnel, schools will be forced to increase health staff without any provisions for reimbursement. She states that schools will face a direct increase in expenditures in order to implement the regulations, resulting in an unfunded mandate.

Response: The State Board notes the comments and disagrees. The proposed regulations provide as much guidance as is possible within the context of the underlying statute. Regarding who may administer medication or render assistance in the administration of medication, the regulations are clear in stating that in order to administer medication (or assist with medication administration), an individual must be legally capable of so doing. To the extent that the comments suggest changing the regulations to make them prescriptive, prescriptive regulations would create a mandate for a higher level of service for which no source of reimbursement funding exists. The underlying statute is discretionary (permissive); no "additional staff" is required to be employed by any local education agency.

Comment 6: Paul Knepprath states, " . . . while we feel that they are an important step in protecting the health of students in California, we are concerned by the extent to which the regulations have been weakened from their original state."

Response: The State Board notes the comment. At the November 2002 meeting of the State Board of Education, the State Board determined to commence the formal rule-making process for regulations relating to the administration of medication (and the providing of assistance with administration of medication) to pupils. The 45-day public review period for the original set of proposed regulations culminated in a public hearing held at the February 2003 meeting of the State Board of Education, at which time the State Board approved a set of amendments to the original proposal to be sent out for 15-day public review. Subsequent to that action, California Department of Education staff collected and analyzed all comments and met with representatives of the Board of Registered Nursing and the state Department of Finance. A second set of amendments was prepared, but staff were advised that the second set of amendments was so extensive as to necessitate withdrawal of the existing rule-making effort and to begin anew. Among the key issues relating to the original regulations were (1) the extent of legal authorization for individuals who do not possess professional health care licenses to administer medication (or provide assistance with the administration of medication) to pupils and (2) at what point(s) the regulations would create a state-mandated local program and, thus, become unapprovable because no reimbursement for the mandate had been funded.

Comment 7: Paul Knepprath states that the regulations allow for "too much variation in interpretation on the part of the local agencies. Further, they do not seem to convey the message sent in Superintendent Eastin's letter, which put the Department of Education on record as encouraging rather than simply allowing proper administration of medication in schools."

Response: The State Board notes the comments. The proposed regulations provide as much guidance as is possible within the context of the underlying statute. To the extent the comments suggest the inclusion of non-binding guidance similar to that found in the Delaine Eastin medication administration letter of 1997, the State Board has provided for issuance and periodic updating of an advisory in Section 611. The advisory would be the appropriate place for non-binding guidance that is of a lengthy nature or identifies specific actions; regulations would not be the appropriate place for guidance of this type.

Comment 8: Debra Back expresses concern related to non-prescription over-the-counter medications. She asks, "Under these regulations, what will happen when a California student takes over-the-counter drugs or supplements without going through the process for administration of medications set forth in these regulations? It is imperative that you provide clarity on this issue; it can have dire consequences for students and parents."

Response: The State Board notes the comments. The authorizing statute clearly identifies the type of medication as "medication prescribed…by a physician" and the regulations clearly allow for "over-the-counter remedies" in the definition of "medication." Hence, if the authorized health care provider prescribes an "over-the-counter" medication, that medication is covered by the regulations. There is no statutory authority to include "non-prescription over-the-counter" medications in these regulations. Likewise, there is nothing in these regulations that would preclude a local education agency from adopting local policies to address the writer's issues.

Comment 9: Kit Dreyfuss notes that the language in the regulations is permissive and asks, "Is this whole process simply making a recommendation and not a mandate?"

Response: The proposed regulations provide as much direction as is possible in relation to the underlying statute. The State Board of Education does not have the authority to create mandates for which no source of reimbursement funding is available.

Comment 10. Debra Back of the Children's Advocacy Institute (CAI) states that it appears that CDE has significantly changed the regulations and intends to shift responsibility for implementing rules and regulations regarding medication administration to local educational agencies. Ms. Back asserts: "CDE has couched the regulations in discretionary language to allow (but not mandate) LEAs to implement rules regarding virtually every component of administering medications at schools. . . The documentation provided by CDE in its proposed rulemaking file does not provide any explanation as to why such a shift in responsibility has occurred or how it can justify the current regulations in light of the specific legislative mandate contained in Education Code section 49423.6(a) for CDE to develop and adopt regulations for administration of medications at school."

Response: The State Board of Education disagrees with the comment. Education Code Section 49423.6 requires the State Board to adopt regulations relating to the administration of medication in the public schools, but within the bounds established by Education Code Section 49423. Education Code Section 49423 is permissive (discretionary), stating that pupils "may be assisted" with medication administration by specified school personnel under specified conditions. Thus, it is the statute itself that places discretionary responsibility on local education agencies, not these regulations.

Comment 11. Debra Back goes on to state that each LEA will now have to create their own rules and regulations on this issue, which will result in fragmented policies that could lead to even more uncertainty on behalf of schools, students, and parents, and disparities between districts.

Response: The State Board of Education disagrees with the comment. The regulations create no new requirements, nor do they require any LEA to establish rules and regulations. To do so would create a state mandated local program. Consistent with the permissive (discretionary) nature of the underlying statute, the regulations merely express authorization to establish local policies consisting of particular elements that have been found to reflect good practices in regard to medication administration and assistance with medication administration. The State Board does not believe existing statute creates authority for it to establish a state mandated local program and, thus, obligate the state to reimburse local education agencies accordingly.

Comment 12. Debra Back also states ". . . it is unclear how these regulations ensure California's compliance with federal law involving students' receipt of necessary medications while at school."

Response: The State Board of Education disagrees with the comment. As stated in section 610, these medication regulations do not alter an LEA's obligations under federal and state laws to special education students and to other students with special health care needs (including the need for medication administration) who qualify under Section 504 of the federal Rehabilitation Act of 1073.

Specific Comments by Section Number
600. Authorization.
Comment 1: Wendy Vaughn asks who is included in the definition of "authorized health care provider," and wonders if the regulations supersede a physician's orders.

Response: The State Board notes the comments. The definition of "authorized health care provider" (included in Section 601) clearly states that such an individual is one licensed by the State of California to prescribe medication. Licensing to prescribe medication is authority outside the purview of the State Board of Education. Thus, this definition is the only practical way the State Board of Education has of describing such an individual.

The proposed regulations cannot (and do not) supersede a physician's orders. The statute itself makes clear that medication administration (or the providing of assistance with medication administration) is to be done within the context of a written statement by a physician or other authorized medical personnel.

601. Definitions.
601(a)
Comment 1: Lydia Bourne suggests deleting "camps or other activities that typically involve at least one overnight stay away from home" from the definition of "regular school day" (line 28).

Response: The State Board disagrees with the comment. The proposed regulations merely make clear that the "regular school day" may include activities that are outside of traditional instructional time (e.g., before- or after-school programs). Therefore, the proposed amendment to delete part of the definition of "regular school day" is not necessary.

Comment 2: Nancy Spradling suggests replacing "may" with "shall" on line 25, the definition of "regular school day."

Response: The State Board disagrees with the comment. Changing "may" to "shall" would create a mandate for a higher level of service for which no source of reimbursement funding is available. Such a change would be inconsistent with the underlying statute, which is discretionary (permissive).

Comment 3: Wendy Vaughn wants to know who determines the definition of "regular school day" and also asks how local education agencies will cover all of the activities included in the definition as proposed.

Response: The State Board notes the comments. The statute itself uses the phrase "regular school day." Local education agencies may view the phrase differently. The proposed regulations merely make clear that the "regular school day" may include activities that are outside of traditional instructional time (e.g., before- or after-school programs). A local education agency choosing to provide medication administration (or assistance with medication administration) to a given pupil outside of traditional instructional time would "cover" this time in the same way that the local education agency would "cover" traditional instructional time, i.e., with an individual who is a licensed health care professional or with a volunteer who is legally authorized to administer medication (or assist with medication administration).

601(b)
Comment 1: Deborah Back wants to know when "over-the-counter" medications are and are not covered by the proposed regulations.

Response: The State Board notes the comments. The authorizing statute clearly identifies the type of medication as "medication prescribed…by a physician," and the regulations clearly allow for "over-the-counter remedies" in the definition of "medication." Hence, if the authorized health care provider prescribes an "over-the-counter" medication, that medication is covered by the regulations.

Comment 2: Judi Baker writes that she is glad to see over-the-counter and herbal remedies included in the regulations.

Response: The State Board notes the comments. No response needed for the comment, as it did not request a change or clarification.

Comment 3: Nancy Spradling suggests replacing "may" with "shall" on line 29, the definition of "medication."

Response: The State Board disagrees with the comment. Such a change would be inconsistent with the underlying statute, which is discretionary (permissive).

Comment 4: Karen Staph Walters suggests adding, "that are included in the health care provider's written statement" after "herbal remedies" on line 31.

Response: The State Board disagrees with the comment. The authorizing statute requires that the school district receive a written statement from the physician in order for the pupil to receive assistance with the medications required during the regular school day. Per the statute, the medication, the method of administration, the amount of the medication, and the time schedule for taking the medication must be specified in the written statement. Therefore, the suggested amendment to the end of line 31 is unnecessary.

Comment 5: Mary Stewart writes that this section needs to be expanded to clarify that herbal medications must be ordered by a California state licensed physician, not an herbalist.

Response: The State Board disagrees with the comment. The definition of "authorized health care provider" (included in Section 601) clearly states that such an individual is one licensed by the State of California to prescribe medication. Licensing to prescribe medication is authority outside the purview of the State Board of Education.

601(d)
Comment 1: James Stone welcomes the provisions of the rule that allows school personnel other than a nurse to administer medications.

Response: The State Board notes the comment. No response needed for the comment, as it did not request a change or clarification.

601(d)(1)
Comment 1: Lydia Bourne suggests adding to the end of line 2, "may maintain a current American Red Cross or American Heart Association certification in cardiopulmonary resuscitation (BCLS)."

Response: The State Board disagrees with the comment. To the extent the comments suggest non-binding guidance for this specific area, the State Board has provided for issuance and periodic updating of an advisory in Section 611. The advisory would be the appropriate place for non-binding guidance that is of a lengthy nature or identifies specific programs; regulations would not be the appropriate place for guidance of this type.

601(d)(2)
Comment 1: Wendy Vaughn wants to know what the term "may legally administer" means. She believes the regulations should clarify who legally can administer medication at school.

Comment 2: Karen Staph Walters requests clarification on what "may legally administer the medication" means.

Comment 3: Marsha Marthaler questions what "may legally administer" means and does not think that the role of designated personnel is clearly addressed.

Response: The State Board notes the comments. The referenced language is clear in stating that in order to administer medication (or assist with medication administration), an individual must be legally capable of so doing. The State Board of Education has no authority to determine the legality of a given individual administering medication (or rendering assistance in the administration of medication). Moreover, the State Board understands that statutes (other than the Education Code) and state agencies (other than itself) do have authority in regard to determining the legality of an individual administering medication (or assisting with the medication administration). The referenced language clearly reflects

those facts. The State Board is unable through regulation to empower an individual in regard to medication administration (or assisting with medication administration) in ways that are contrary to statute or to the authority of other state agencies. Furthermore, in a practical sense, the State Board cannot list in these regulations all of those categories of individuals who may administer medication (or assist with the administration of medication). Even if accurate at the time of approval, such a list would become inaccurate or incomplete in short order.

The "role" of designated personnel (which presumably means personnel other than school nurses) is clear: They may administer medication to pupils (or assist pupils with the administration of medication) "as allowed by law," presuming the personnel have volunteered (consented) to do so.

Comment 4: Nancy Spradling suggests replacing "may" with "can" on line 3 because "The definition of other designated school personnel who are legally able to administer medication is not permissive."

Response: The State Board disagrees with the comment. "May" and "can" are frequently interchangeable and denote possibility. Therefore, replacing "may" with "can" would serve no purpose in these regulations.

601(g)
Comment 1: Both Vicki Bermudez and Nancy Spradling suggest replacing "may" with "shall" in the description of what is to be included in the medication record.

Response: The State Board disagrees with the comments. Changing "may" to "shall" would create a mandate for a higher level of service for which no source of reimbursement funding is available. Such a change would be inconsistent with the underlying statute, which is discretionary (permissive).

601(g)(4)
Comment 1: Lydia Bourne suggests adding to the end of line 14, "to include possible side effects and/or other effects and action required if they occur."

Response: The State Board disagrees with the comment. To the extent the comments suggest non-binding guidance for this specific area, the State Board has provided for issuance and periodic updating of an advisory in Section 611. The advisory would be the appropriate place for non-binding guidance that is of a lengthy nature or identifies specific actions; regulations would not be the appropriate place for guidance of this type.

601(h)
Comment 1: Both Vicki Bermudez and Nancy Spradling suggest replacing "may" with "shall" in the description of what information belongs in the medication log.

Response: The State Board disagrees with the comment. The suggested change would create a mandate upon those local education agencies choosing to maintain a medication log. In so doing, the suggestion would create a higher level of service for which no source of reimbursement funding is available.

Comment 2: Lydia Bourne suggests adding a ninth item to the list of what the medication log may include. That item would be "Notation for possible side effect(s), action taken and outcome."

Response: The State Board disagrees with the comment. To the extent the comments suggest non-binding guidance to the optional medication log, the State Board has provided for issuance and periodic updating of an advisory in Section 611. The advisory would be the appropriate place for non-binding guidance that is of a lengthy nature or identifies additional specific actions.

602. Written Statement of Authorized Health Care Provider.
602(a)
Comment 1: Nancy Spradling suggests adding "While a local education agency shall not be mandated to assist in administering medications, if they choose to do so, then..." on line 31 and also changing "may" to "shall" on line 31. She suggests that because the local education agency would be free to choose whether or not to assist in administering medication, this suggested wording would not create a mandate.

Response: The State Board disagrees with the comment. The proposed regulations provide as much direction as is possible in relation to the underlying statute. Stating that if the local education agency chooses to administer medication then requiring them to follow specific actions would create mandates for higher levels of service for which no source of reimbursement funding is available.

602(a)(3)
Comment 1: Lydia Bourne suggests that the method for medication administration be added to the health care provider's written statement.

Response: The State Board disagrees with the comment, as the addition is not necessary. If the medication is prescribed, then the label affixed by the pharmacist will state the method of administration. If the medication is an over-the-counter remedy, then the container will indicate the method of administration. If, in any given case, there is something unusual or not plainly evident about the method of administration, then the authorized health care provider will include that as "other information" in the written statement.

Comment 2: Lydia Bourne suggests that the regulations be amended to state that prior to the first administration of medication or when there has been a medication change order, the physician's written statement may be reviewed by a duly qualified supervisor of health, who will determine who is the most appropriate provider of the medication and what level of supervision is required.

Response: The State Board disagrees with the comment. Nothing in the proposed regulations prohibits a local education agency from adopting a procedure for the review of authorized health care providers' written statements by a duly qualified supervisor of health. Therefore, the additional authorization suggested in this comment is unnecessary. Requiring such review would constitute a mandate for a higher level of service for which no source of reimbursement is available.

602(b)
Comment 1: Nancy Spradling suggests replacing "may" with "should" on line 4.

Response: The State Board disagrees with the comment. Changing "may" to "should" would create a mandate for a higher level of service for which no source of reimbursement funding is available. Such a change would be inconsistent with the underlying statute, which is discretionary (permissive).

602(c)
Comment 1: Nancy Spradling suggests replacing "may" with "should" on line 7.

Response: The State Board disagrees with the comment. Again, changing "may" to "should" would create a mandate for a higher level of service for which no source of reimbursement funding is available. Such a change would be inconsistent with the underlying statute, which is discretionary (permissive).

603. Written Statement of the Parent or Legal Guardian.
603(a)
Comment 1: Karen Schenck expresses concern that sometimes parents request medication to be given "as needed."

Response: The State Board notes the concern. However, these regulations pertain to medication that is prescribed by the authorized health care provider and, as authorized by statute, require that a written statement from the authorized health care provider state the medication the pupil is to take, the dosage, and the period of time during which the medication will be taken, as well as detailing (as necessary) the method, amount and time schedule by which the medication is to be taken. The parent or legal guardian statement merely initiates the request to the school district to have the pupil assisted with medication administration as prescribed by the authorized health care provider.

Comment 2: Nancy Spradling suggests adding "While a local education agency shall not be mandated to assist in administering medications, if they choose to do so, then…..."… on line 13 and also replacing "may" with "shall" on line 13. She suggests that because the local education agency would be free to choose whether or not to assist in administering medication, this suggested wording would not create a mandate.

Response: The State Board disagrees with the comment. The proposed regulations provide as much direction as is possible in relation to the underlying statute. Stating that if the local education agency chooses to administer medication then requiring them to follow specific actions would create mandates for higher levels of service for which no source of reimbursement funding is available.

603(a)(2)
Comment 1: Mary Davidson suggests that "credentialed school nurse," and "site administrator" be listed in addition to "an authorized representative of the local education agency" as appropriate individuals to communicate with the pupil's authorized health care provider.

Response: The State Board disagrees with the comment. The proposed additions of "credentialed school nurse" and "site administrator" are unnecessary, as these individuals would be examples of authorized representatives of the local education agency (and all authorized representatives are already included). Moreover, the proposed additions use somewhat different references to these individuals than the references used elsewhere in the regulations.

Comment 2: Lydia Bourne suggests replacing "an authorized representative of the local education agency" on line 16 with "the duly qualified supervisor of health."

Response: The State Board disagrees with the comment. Nothing in the proposed regulations prohibits a local education agency from appointing a duly qualified supervisor of health to communicate with the pupil's authorized health care provider. Therefore, the additional authorization suggested in this comment is unnecessary. Specifying such an individual would constitute a mandate for a higher level of service for which no source of reimbursement is available.

603(a)(5)
Comment 1: Lydia Bourne requests clarification on how the parent/guardian will understand how they may terminate consent for medication administration.

Response: The State Board notes the comment. The regulations give authority to the local education agency to establish specifications for the parent or guardian's written statement to ensure a specified list of actions. There is no need for the State Board to develop additional detail as the authority to develop this level of detail has already been given to the local education agency.

603(b)
Comment 1: Judi Baker suggests that "proper container" be replaced with "original container" or "container provided by the pharmacist."

Response: The State Board disagrees with the comment. "Proper container" as used in the proposed regulations is the appropriate reference. "Container provided by the pharmacist" would not apply to all types of medication that may be administered (or for which pupils may receive assistance with administration). "Original container" could be interpreted as taking away important discretion to refuse to administer medication in the "original container" if, for example, that container has been damaged in such a way as to compromise the contents. In such a circumstance, the medication, while in the "original container," would not be in a "proper container."

Comment 2: Vicki Bermudez suggests replacing "may" with "shall" on line 30 (which would then state "A local education agency shall provide reasonable accommodations. . .), replacing "reasonable accommodations" with "assistance" on line 30, and adding "such" in front of "assistance" on line 31.

Response: The State Board disagrees with the comment. Changing "may" to "shall" would create a mandate for a higher level of service for which no source of reimbursement funding is available. Such a change would be inconsistent with the underlying statute, which is discretionary (permissive). "Reasonable accommodations" is the appropriate reference in this context. It subsumes and goes beyond the narrower reference suggested. "Linguistically and culturally appropriate assistance," for example, might be interpreted as excluding assistance in the form of transcribing an oral statement made by a disabled individual who is unable to hold a writing instrument or manipulate a keyboard. Such a disabled individual would not necessarily be challenged by a linguistic or cultural barrier, only a physiological barrier. Adding "such" in front of "assistance" does not add meaning or clarification to the section.

Comment 3: Lydia Bourne suggests replacing "reasonable accommodations" on line 30 with "linguistically and culturally appropriate assistance."

Response: The State Board disagrees with the comment. As stated in the response to ***603(b) Comment 2,*** *"reasonable accommodations" is the appropriate reference in this context. It subsumes and goes beyond the narrower reference suggested. "Linguistically and culturally appropriate assistance," for example, might be interpreted as excluding assistance in the form of transcribing an oral statement made by a disabled individual who is unable to hold a writing instrument or manipulate a keyboard. Such a disabled individual would not necessarily be challenged by a linguistic or cultural barrier, only a physiological barrier.*

604. Administration of Medication to Pupils or Otherwise Assisting Pupils in the Administration of Medication.

Comment 1: Judy Baker writes "typically we have yearly trainings of secretaries about medication administration. Is this no longer mandated?

Response: The State Board notes the comment. There is no statutory authority or requirement to do a yearly training of secretaries about medication administration. There is nothing in the regulations that would prohibit such local practice.

Comment 2: Judy Baker wonders if it was the intent of this section to limit administration of medication to a health care professional. She is concerned that there is no mention of other school personnel administering the medication unless designated by a parent.

Response: The State Board notes the comment. Section 604(b) is clear. Because the statute itself separately lists "school nurse" as a category of individuals who may administer medication (or render assistance with medication administration), they are covered in subdivision (a) of Section 604. Subdivision (b) of that section, therefore, covers "other designated school personnel," the other category

listed in statute, and that phrase ("other designated school personnel") is specifically defined in Section 601(d).

Comment 3: Judy Baker is also concerned that there is "no mention of specific drugs such as insulin which could only be administered by a nurse. The whole issue of diabetic medications/supplies should be addressed separately."

Response: The State Board notes the comment. Creation of a section of the regulations limiting to certain individuals the authority to administer (or render assistance with) certain medications is unnecessary, and would likely go beyond the scope of the statutory authority. The regulations already speak to all individuals (whether or not professionally licensed) administering (or rendering assistance with) medication doing so only "as allowed by law." Creating a point-in-time list of authorized or excluded individuals in relation to specific medications is, therefore, unnecessary. Moreover, unless the list was precisely in line with other legal authority, its existence could create a mandate for a higher level of service for which no reimbursement funding is available.

Comment 4: Judy Baker also believes this section should discuss what to do about students who don't come in to take their medication so the liability won't be the school's.

Response: The State Board disagrees with the comment. The proposed regulations provide as much direction as is possible in relation to the underlying statute. This addition is not necessary. There is nothing in the regulations that would prohibit a local education agency from developing a local policy related to interventions with students who do not appropriately take medication prescribed for them at school and protecting the local education agency in such instances.

Comment 5: Marsha Mathaler states that she "would like to see certain meds that may need more specialized training, assessment, and care addressed."

Response: The State Board notes the comment. There is no statutory authority to single out specific medications. Additionally, creating a point-in-time list of certain medications that may need more specialized training, etc., would be ill-advised because the list would likely be out-of-date very quickly. Moreover, unless the list was precisely in line with other legal authority, its existence could create a mandate for a higher level of service for which no reimbursement funding is available.

604(a)

Comment 1: Wendy Vaughn wants to know what "as allowed by law" means; what "legal provisions" are invoked, what the "applicable standards of professional practice" are, and who determines what standards apply. She also states, "We understand that according to the Board of Nurse Practitioners, the standard of care may vary across the state in terms of rural and urban locations. Standards of professional practice should be consistent across the state and readily referenced if this regulation is to assist school districts. Does this provision imply that urban school districts will have increased costs and be held to higher standards of care?"

Response: The State Board notes the comments. "As allowed by law" is the only reasonable means the State Board of Education has of taking into account the existence of statutes (outside of the Education Code) and the authority of other state agencies that regulate medication administration (and the rendering of assistance with medication administration). It is not practical to create in regulation lists detailing every circumstance under which medication administration is lawful or unlawful at a school site. "Applicable standards of professional practice" is a phrase used in the proposed regulations only in relation to specifically licensed health care professionals. Such individuals (in their capacities as licensees of the state) will understand the meaning of the phrase and will know what they are permitted and not permitted to do. Standards of professional practice are generally established by the various state

licensing boards for health care professions (e.g., Board of Dental Examiners, Medical Board of California, Board of Optometry, and Board of Registered Nursing).

604(b)

Comment 1: Karen Schenck expresses serious concern, as a school principal, about office staff administering insulin injections and the legal aspect of "offering advice without a medical degree." She expresses concern about field trips and also asks, "What legislation covers giving insulin shots?"

Response: The State Board notes that this comment is effectively beyond the scope of the proposed regulations. These regulations speak only to individuals (whether or not professionally licensed) administering medication or rendering assistance with medication administration "as allowed by law." If the commenter is concerned that too many individuals are allowed by law to administer insulin, he or she needs to take up that matter with authorities other than the State Board of Education. These regulations speak only to the prospect of non-professionally-licensed school staff administering any medication (regardless of the means) "as allowed by law." Moreover, nothing in the regulations condones or promotes offering medical advice without a medical degree.

Comment 2: Elaine Cash interprets lines 4 - 6 as stating that only licensed health care professionals are able to administer medications and asks, "Who other than a doctor, nurse or physician's assistant qualifies as a licensed health care professional?"

Response: The State Board notes the comments. "As allowed by law" (like "may legally administer") is the only reasonable means the State Board of Education has of taking into account the existence of statutes (outside of the Education Code) and the authority of other state agencies that regulate medication administration (and the rendering of assistance with medication administration) and the personnel so authorized to administer or assist with medication administration. The "role" of designated personnel (which presumably means personnel other than school nurses or other health care professionals) is clear: They may administer medication to pupils (or assist pupils with the administration of medication) "as allowed by law," presuming the personnel have volunteered (consented) to do so.

Comment 3: Wendy Vaughn restates the same concern she stated in Section 604(a), asking "Again, what does 'as allowed by law' mean in this context and what legal provisions are invoked? What are the 'applicable standards of professional practice' for this provision?"

Response: The State Board notes the comments. "As allowed by law" (like "may legally administer") is the only reasonable means the State Board of Education has of taking into account the existence of statutes (outside of the Education Code) and the authority of other state agencies that regulate medication administration (and the rendering of assistance with medication administration) and the personnel so authorized to administer or assist with medication administration. The "role" of designated personnel (which presumably means personnel other than school nurses or other health care professionals) is clear: They may administer medication to pupils (or assist pupils with the administration of medication) "as allowed by law," presuming the personnel have volunteered (consented) to do so.

"Applicable standards of professional practice" is a phrase used in the proposed regulations only in relation to specifically licensed health care professionals. Such individuals (in their capacities as licensees of the state) will understand the meaning of the phrase and will know what they are permitted and not permitted to do. Standards of professional practice are generally established by the various state licensing boards for health care professions (e.g., Board of Dental Examiners, Medical Board of California, Board of Optometry, and Board of Registered Nursing).

604(c) and 604(d)
Comment 1: Wendy Vaughn again wonders what "as allowed by law" means and what legal provisions are invoked.

Response: The State Board notes the comment. "As allowed by law" (like "may legally administer") is the only reasonable means the State Board of Education has of taking into account the existence of statutes (outside of the Education Code) and the authority of other state agencies that regulate medication administration (and the rendering of assistance with medication administration) and the personnel so authorized to administer or assist with medication administration.

605. Self-Administration of Medication.
Comment 1: Lydia Bourne suggests that the local education agency should consult with the duly qualified supervisor of health and the student's health care provider when establishing rules governing self-administration.

Response: The State Board notes the comments. Nothing in the proposed regulations precludes a local education agency's duly qualified supervisor of health and/or the student's health care provider from being involved in establishing policies or rules governing self-administration of medication. Therefore, authorization for such involvement need not be included in these regulations. Requiring such involvement would constitute a mandate for a higher level of service for which no source of reimbursement funding exists and, therefore, could not be included in these regulations.

Comment 2: Mary Davidson suggests that the site administrator, with input from the school nurse or student's teacher, should make the final decision concerning a student's ability to self medicate and carry their own medication at school.

Response: The State Board notes the comment. Nothing in the proposed regulations precludes a local education agency from establishing policies or rules under which the school nurse and/or a pupil's teacher(s) are involved in discussions regarding self-administered medication (presuming no complicating issue is involved, e.g., doctor-patient confidentiality). Therefore, authorization for such involvement need not be included in these regulations. Requiring such involvement would constitute a mandate for a higher level of service for which no source of reimbursement funding exists and, therefore, could not be included in these regulations.

Comment 3: Nancy Spradling suggests replacing "may" with "shall" on lines 25 and 27, making the text read, "A local education agency shall establish rules governing self-administration. . . Through such rules, a local education agency shall describe circumstances under which self-administration may be prohibited."

Response: The State Board disagrees with the comment. The suggested change would create a mandate upon those local education agencies choosing to allow students to self-administer medication. In so doing, the suggestion would create a higher level of service for which no source of reimbursement funding is available.

Comment 4: James Stone believes this section gives local officials "carte blanche to make children with diabetes go to the nurse's office…" to administer insulin. He suggests that language be added to clarify that limits should only be imposed if a real danger exists.

Response: The State Board disagrees with the comment. To the contrary, the establishment of locally approved rules regarding self-administration (as envisioned in this section of regulations) is specifically tied to protecting "the health and safety both of the pupil and of the whole student body and staff at the school site." The authorization for local rules, by its own terms, is not envisioned as "carte blanche."

The suggested addition of a reference to "real danger" would not substantively change the meaning of the existing reference to health and safety protection.

606. Delivery and Storage of Medication.

Comment 1: Nancy Spradling suggests adding "While a local education agency shall not be mandated to assist in administering medications, if they choose to do so, then a local education agency shall. . ." on lines 31-32. She suggests that because the local education agency would be free to choose whether or not to assist in administering medication, this suggested wording would not create a mandate.

Response: The State Board disagrees with the comment. The proposed regulations provide as much direction as is possible in relation to the underlying statute. Stating that if the local education agency chooses to administer medication then requiring them to follow specific actions would create mandates for higher levels of service for which no source of reimbursement funding is available.

607. Documentation.

Comment 1: Vicki Bermudez suggests replacing "may" with "shall" on line 1 and adding "consistent with Sections 600-611" in front of "regarding." This would make the text read, "A local education agency shall establish policies consistent with Sections 600-611 regarding documentation of the administration of medication to pupils. . ."

Response: The State Board disagrees with the comment. Changing "may" to "shall" would create a mandate for a higher level of service for which no source of reimbursement funding is available. Such a change would be inconsistent with the underlying statute, which is discretionary (permissive).

Comment 2: Lydia Bourne states that this section is woefully inadequate and says the following questions should be addressed: (1) What is the procedure for reviewing the medication log? (2) Who has authority for making notations? (3) How will pupil confidentiality be maintained? (4) How is a child to receive medication identified? (5) If medication administration doesn't occur, what is the procedure for documenting this and the procedure for handling such an occurrence? (6) What is the procedure for handling and administering controlled substances? (7) Is there or will there be a procedure for medication administration when on school sponsored trips?

Response: The State Board disagrees with the comment. To the extent the comments suggest the inclusion or exclusion of specific individuals in regard to specific tasks, the changes in the regulations would constitute a mandate for a higher level of service for which no source of reimbursement exists. To the extent the comments suggest non-binding guidance for this specific area (self-administration), the State Board has provided for issuance and periodic updating of an advisory in Section 611. The advisory would be the appropriate placed for non-binding guidance that is of a lengthy nature; regulations would not be the appropriate place for lengthy guidance of this type.

Comment 3: Nancy Spradling suggests adding "While a local education agency shall not be mandated to assist in administering medications, if they choose to do so, then a local education agency shall. . ." on lines 1-2. She suggests that because the local education agency would be free to choose whether or not to assist in administering medication, this suggested wording would not create a mandate.

Response: The State Board disagrees with the comment. The proposed regulations provide as much direction as is possible in relation to the underlying statute. Stating that if the local education agency chooses to administer medication then requiring them to follow specific actions would create mandates for higher levels of service for which no source of reimbursement funding is available.

608. Deviation from Authorized Health Care Provider's Written Statement.

Comment 1: Lydia Bourne is concerned about the lack of guidance and suggests that there be more stringent regulations for local education agencies to follow in the case of medication errors.

Response: The State Board disagrees with the comment. The proposed regulations provide as much direction as is possible in relation to the underlying statute. "More stringent regulations" could only be established by creating mandates for higher levels of service for which no source of reimbursement funding is available.

Comment 2: Nancy Spradling suggests adding "While a local education agency shall not be mandated to assist in administering medications, if they choose to do so, then a local education agency shall. . ." on lines 9-11. She suggests that because the local education agency would be free to choose whether or not to assist in administering medication, this suggested wording would not create a mandate.

Response: The State Board disagrees with the comment. The proposed regulations provide as much direction as is possible in relation to the underlying statute. Stating that if the local education agency chooses to administer medication then requiring them to follow specific actions would create mandates for higher levels of service for which no source of reimbursement funding is available.

608(a)

Comment 1: Wendy Vaughn wants to know what "applicable standards of professional practice" mean in this context, who determines the standards, and what the standards are.

Response: The State Board notes the comment. "Applicable standards of professional practice" is a phrase used in the proposed regulations only in relation to specifically licensed health care professionals. Such individuals (in their capacities as licensees of the state) will understand the meaning of the phrase and will know what they are required and not required to do. Standards of professional practice are generally established by the various state licensing boards for the health care professions (e.g., Board of Dental Examiners, Medical Board of California, Board of Optometry, and Board of Registered Nursing).

609. Unused, Discontinued and Outdated Medication.

Comment 1: Vicki Bermudez recommends changing "may" to "shall" in line 19, making the passage read, "A local education agency shall establish policies regarding unused, discontinued, and outdated medication. . ."

Response: The State Board disagrees with the comment. Changing "may" to "shall" would create a mandate for a higher level of service for which no source of reimbursement funding is available. Such a change would be inconsistent with the underlying statute, which is discretionary (permissive).

Comment 2: Similarly, Nancy Spradling suggests adding "While a local education agency shall not be mandated to assist in administering medications, if they choose to do so, then a local education agency ..." and replacing "may" with "shall" on line 19.

Response: The State Board disagrees with the comment. Section 6 of Article XIIIB of the California Constitution provides that whenever a state agency (e.g., through regulation) mandates a new program or a "higher level of service" on a local government agency, the state must reimburse the local agency accordingly. Thus, if this suggestion were to be incorporated in the regulations, the result would be the creation of a reimbursable state mandate to the extent that a local education agency might choose to administer medication (or assist with medication administration), but not voluntarily implement all of the provisions of this section. In other words, when a program or activity is (per se) discretionary (permissive), then each of the components potentially included in the program or activity is similarly

discretionary. Requiring that a whole set of components be provided if any portion of a discretionary program or activity is undertaken creates a reimbursable state mandate to the extent that any of the components is not voluntarily included by the local agency. The non-voluntary components would reflect a mandatory higher level of service.

610. Applicability of This Article.

Comment 1: James Stone does not feel that this section states clearly enough that local education agencies may be required to administer medications to certain students in accordance with Section 504 and that as worded, it may be burdensome (as defined in Government Code section 11346.5(a)(13) to parents of children eligible for 504 accommodations.

Response: The State Board disagrees with the comment. This section helps emphasize that the underlying statute is discretionary (permissive) and states the fact that other enumerated statutes and regulations (within the Education Code and other codes) may be pertinent to the topic of medication administration (or rendering assistance with medication administration) in regard to individual pupils. This section does not change (or purport to change) any requirements of Section 504 of the Rehabilitation Act of 1973. A parent or legal guardian may pursue development of a Section 504 Accommodation Plan and, if he or she does so, must follow all applicable requirements pertaining thereto. There is no need to restate here all of the potentially pertinent requirements of Section 504. The section is clear as written; no change is necessary.

610(d)
Comment 1: Wendy Vaughn wants to know if federal law supercedes state law in relation to medication administration.

Response: The State Board notes that this comment is effectively beyond the scope of these regulations. As stated at the beginning of section 610, these medication regulations do not alter the content or implementation of a pupil's individualized education program or Section 504 Accommodation Plan that has been prepared in accordance with federal and state laws.

611. Issuance and Periodic Updating of Advisory.
Comment 1: Vicki Bermudez suggests deleting this section because this section would permit the issuance of underground regulations in the guise of "non-binding guidance."

Response: The State Board disagrees with the comment. No foundation is established for this contention. To the contrary, Section 611(by its own terms) requires that any guidance provided in the advisory must be "non-binding." Moreover, the reference cited for this provision (Education Code Section 33308.5) allows for the issuance only of guidelines that "are merely exemplary." This section of law is typically cited in California Department of Education publications of the type envisioned in this regulation within the context of a statement along the following lines, "The guidance in [name of document] is not binding on local educational agencies or other entities. Except for the statutes, regulations, and court decisions that are referenced herein, the document is exemplary, and compliance with it is not mandatory."

Comment 2: Karen Staph Walters recommends deleting this section. She states that the *Education Code* sections cited do not describe nor require such an advisory, and a non-binding advisory may actually confuse local education agencies since the proposed regulations themselves are "advisory."

Response: The State Board disagrees with the comment. Education Code Section 49423.6 requires the State Board of Education to adopt regulations "regarding the administration of medication in the public schools pursuant to [Education Code] Section 49423." The State Board believes that an advisory would be necessary or beneficial to carrying out its responsibilities under Education Code Section 49423.6.

Therefore, it is perfectly reasonable to include this provision in the regulations. There is no evidence to support the view that an advisory would confuse local education agencies. The State Board retains approval authority over the advisory to ensure (among other things) that the advisory is consistent with applicable statutes and regulations and promotes clarity in relation to the regulations.

Comment 3: Wendy Vaughn believes that because the regulations do not provide clear guidance, they may consequently cause local education agencies to have to hire additional staff because of disputes about the meaning of the regulations.

Response: The State Board disagrees with the comment. The proposed regulations provide as much guidance as is possible within the context of the underlying statute. Prescriptive regulations would create a mandate for a higher level of service for which no source of reimbursement funding exists. The underlying statute is discretionary (permissive); no "additional staff" is required to be employed by any local education agency.

ALTERNATIVES DETERMINATION

The State Board has determined that no alternative considered by the agency would be more effective in carrying out the purpose for which the regulation is proposed or would be as effective and less burdensome to affected private persons than the adopted regulation.

LOCAL MANDATE DETERMINATION

The proposed regulations do not impose any mandate on local agencies or school districts.

REQUEST THAT REGULATIONS BECOME EFFECTIVE UPON FILING

The State Board requests that OAL permit the regulations in the current rulemaking file to become effective upon filing (as indicated in Section B5 of the Form 400). Due to several delays, including twice needing to rewrite the regulations and reassignment of the staff responsible for the regulations due to the long term illness of original staff, these regulations are long overdue. Education Code section 49423.6 provides for the adoption of these regulations on or before June 15, 2001.