The following comment letters are in support of the regulatory proposal:

Letter 1
Commenter
Robert Ford, CRNA
Organization
Professional Nursing Association

Letter 2
Commenter
Dianne Moore, PhD, MN, MPH, CNM, RN
Title
Associate Provost
Organization
Nursing Education and Regulatory Affairs,
West Coast University

Letter 3
Commenter
Charles Griffis, CRNA, PhD
Title
Associate Professor
Organization
UCLA School of Nursing and Anesthesiology

Letter 4
Commenter
Maureen Wolfe
Title
Midwife

Letter 5
Commenter
Sarah Shealy, RN, CNM, MSN, IBCLC
Title
Assistant Professor, Director
Organization
Accelerated BSN Program
Mount Saint Mary's College
Doheny Campus

Letter 6
Commenter
Caryn Crespo, CNM, MSN, GWHNP

Letter 7

Commenter
Honorable Tricia Hunter, RN, MN
Title
Executive Director
Organization
American Nurses Association – California

Letter 8
Commenter
Joe Janakes, CRNA, MSN
Title
President
Organization
California Association of Nurse Anesthetists

Letter 9
Commenter
Surani Kwan
Title
President
Organization
California Association of Nurse Practitioners

Letter 10
Commenter
Jenny Lu, RN, MSN, PNP

Letter 11
Commenter
Kim Q. Dau
Title
Co-Chair
Organization
Health Policy
California Nurse-Midwives Association

Additional Comments Received

Comment Letter 6 (Laurel Bernstein, RN, MPH)
Comment
I am writing to comment on the proposed changes to CA code of Regulations Title: 22, sections 51240, 51305, and 51476. Nurse-Midwives and Nurse Practitioners have been shown in the literature to have patient outcomes that are equal or superior to those of physicians. Current physician to NP ratios are sufficiently restrictive to ensure patient safety. Medi-Cal should have regulations that are in line with those set by other state

regulatory agencies to decrease waste and ensure that primary care is available to all CA residents. I encourage policy makers to consult the scientific literature and favor that information over political pressures from physicians who fear losing power and money, both of which come at the cost of patient care.

Response

This comment appears to request what is being proposed through this regulatory action. Specifically, that the scope and standards of practice for Medi-Cal NMPs will reside in the appropriate location, under each provider's applicable professional licensing statutes and regulations, thus eliminating impermissible conflict with and unnecessary duplication of provisions under the B&P Code; Title 16, CCR, Division 2; and Title 22, CCR, Division 3.

Comment Letter 13 (California Nurses Association)

Comment #1

On behalf of the 86,000 registered nurse members of the California Nurses Association (CNA), we are submitting recommendation for modifications of some of the proposed changes to Title 22, California Code of Regulations § 51305 and §51476. We appreciate the opportunity to submit comments on these proposed changes and commend the Department of Health Care Services (DHCS) for updating these sections to eliminate impermissible conflict with and unnecessary duplication of provisions under the Business and Professions Code (B&P). We have reviewed the regulatory package DHCS-06-017 Nonphysician Medical Practitioners (NMPs) and respectfully propose some modifications.

§51305 Physician Services

(k) Primary care physician services rendered by nonphysician medical practitioners are covered as physician's services to the extent permitted by applicable professional licensing statutes and regulations, and as set forth in the Physician-Practitioner Interface as described in Section
51240.

(1) Services and entries in the patient's health record by [Begin Strikeout]~~non-physician~~[End Strikeout] nonphysician medical practitioners shall be reviewed by the primary care physician [Begin Strikeout]~~within seven calendar days of the date of service~~[End Strikeout] [Begin Underline]to the extent required by the applicable professional licensing statutes and regulations. [End Underline]

The proposed modifications lacks clarity and consistency. "Clarity" means written or displayed so that the meaning of regulations will be easily understood by those persons directly affected by them.

"Consistency" means being in harmony with, and not in conflict with or contradictory to, existing statutes, court decision, or other provisions of law?

Nurse Practitioners (NP) and Certified Nurse Midwives (CNM) engage in primary care practice under Standardized Procedures. There is not a requirement for review of a patient's health record by primary care physicians in either statute or regulation for NPs or CNMs, unlike the statutes and regulations under which a Physician Assistant (PA) practices. If (k)(1) is modified as proposed, it will read, *"Services and entries in the patient's health record by nonphysician medical practitioners shall be reviewed by the primary care physician to the extent required by the applicable professional licensing statutes and regulation. "*

This is confusing in that physicians are not required to review the patient's health record by professional licensing statutes or regulations for NPs or CNMs and yet the language, as proposed, sets up that expectation. The only question seems to be what "extent" it is required and for that one must refer to the professional licensing statutes and regulations for NPs and CNMs.

16 CCR §1474 Standardized Procedure Guidelines states, in pertinent part:

(b) Each standardized procedure shall:

(1) Be in writing, dated and signed by the organized health care system personnel authorized to approve it.

(2) Specify which standardized procedure functions registered nurses may perform and under what circumstances.

(3) State any specific requirements which are to be followed by registered nurses in performing particular standardized procedure functions.

(4) Specify any experience, training, and/or education requirements for performance of standardized procedure functions.

(5) Establish a method for initial and continuing evaluation of the competence of those registered nurses authorized to perform standardized procedure functions.

(6) Provide for a method of maintaining a written record of those persons authorized to perform standardized procedure functions.

(7) Specify the scope of supervision required for performance of standardized procedure functions, for example, immediate supervision by a physician.

(8) Set forth any specialized circumstances under which the registered nurse is to immediately communicate with a patient's physician concerning the patient's condition.

(9) State the limitations on settings, if any, in which standardized procedure functions may be performed.

10) Specify patient record keeping requirements

(11) Provide for a method of periodic review of the standardized procedures.

16 CCR §1474 does not answer the question implied in the proposed language which is: To what extent is a primary care physician required to review the health record of patients under the care of NPs or CNMs?

However, 22 CCR §51240(d) states, in pertinent part:
Each primary care physician organized outpatient clinic or hospital outpatient department which utilizes a nonphysician medical practitioner shall develop a [Begin Italics]*Physician-Practitioner Interface specifically establishing the scope and limits of services to be rendered by, and related to the functions of, each nonphysician medical practitioner.*[End Italics] [Emphasis added]

(1) A Physician-Practitioner Interface includes the following:

(A) In the case of registered nurses, standardized procedures, as required by Title 16, Article 7, Division 14, California Code of Regulations, commencing with Section 1470.

(B) In the case of physician assistants, a written delegation of medical services and written supervisory guidelines, as required by Section 1399.540 and Section 1399.545(e), Title 16, California Code of Regulations.

(C) All written protocols issued by collaboration between the physician and the nonphysician medical practitioner.

(D) All written standing orders of the physician.

(E) All written special orders given by the physician.

This portion of 22 CCR § 51240 is clear, unambiguous and consistent with statues and regulations for NP, CNMs and PAs. 22 CCR §51305 (k) is clear, unambiguous and consistent with statutes and regulations for NPs, CNMs and PAs and its reference to 22 CCR§ 51240 comprehensively addresses the requirements for primary care physician and NMP collaboration/supervision using vehicles consistent with the applicable professional licensing statues and regulations. If there is to be primary care physician review of a patient's health record for services provided by an NP or CNM, that requirement (although not required by statute or regulations) would be a part of the Physician-Practitioner Interface. Since Section 51305(k) already refers to the Physician-Practitioner Interface, (k)(1) serves no purpose under Physician Services. CNA respectfully suggests the following modification to Section 51305 (k):

(k)Primary care physician services rendered by nonphysician medical practitioners are covered as physician's services to the extent permitted by applicable professional

licensing statutes and regulations, and as set forth in the Physician-Practitioner Interface as described in Section 51240.

[Begin Strikeout] ~~(1) Services and entries in the patient's health record by nonphysician medical practitioners shall be reviewed by the primary care physician within seven calendar days of the date of service to the extent required by the applicable professional licensing statutes and regulations.~~ [End Strikeout]
Section 51305(k)(2), (3), (4), and (5) would be renumbered, (1), (2), (3) and (4) respectively.

Response to Comment #1
The Department is proposing to remove requirements and/or restrictions that were placed on NMPs for participation in the Medi-Cal Program that were covered in the standards of practice established by the Medical Practice Act, Nursing Practice Act, and Physician Assistant Practice Act, which are set forth in B&P Code Sections 2000 et seq.; 2700 et seq; and 3500 et seq., respectively and implementing regulations under Title 16, Division 2, CCR. These standards are in accordance with the authority and jurisdiction of the applicable licensing boards. The amendments proposed through this regulatory action will maintain the scope and standards of practice for Medi-Cal NMPs in the appropriate location, under each provider's applicable professional licensing statutes and regulations, as described above. This will eliminate impermissible conflict with and unnecessary duplication of provisions under the B&P Code; Title 16, CCR, Division 2; and Title 22, CCR, Division 3. This will also avoid the need to revise these regulations when the scope or standards of practice for these providers change through B&P Code and/or Title 16 changes.

Section 51305(k) establishes provisions related to overall "physician services" rendered by an NMP; paragraph (1) is designed as a subcategory of (k) and is specific to the review of patient health records.

As proposed subsection (k)(1), includes a cross reference to applicable NMP professional licensing statutes and regulations, maintaining NMP scope and standards in the appropriate location. This cross reference includes Title 16, Division 14, Article 7 *(Standardized Procedure Guidelines),* CCR commencing with Section 1470, as specified under Section 51240(d)(1)(A) as part of the Physician-Practitioner Interface, which specifies the functions, scope and limits of NMP services.
The language proposed under subsection (k)(1) is consistent with a fundamental purpose of this regulatory proposal, which is avoiding unnecessary revisions to the regulations if the (extent/amount/scope) of standards for any of these providers is amended through the B&P Code and/or Title 16, including provisions related to patient health record review.

The term "extent" is existing language under Sections 51305(k) and 51476(a) and is proposed under Section 51305(k)(1).
Merriam Webster's Online Dictionary defines "extent" as the point, degree or limit to which something extends; Burton's Legal Thesaurus – 3rd ed., 1998 specifies

synonyms such as “scope” and “amount.” As described, this term can commence at a level of “zero” or “nothing” and can increase from that point on *(i.e. if there is nothing on point, the “extent” in that scenario is zero)*. The use of this term, under Section 51305(k)(1) is appropriate and provides necessary flexibility in consideration of changing statutes and regulations.

NP and CNM providers, as well as their related professional associations have voiced considerable support for this regulatory proposal, without any noted concerns.

Comment #2
The CDHCS also proposes to modify Section 51476 which states, in pertinent part:

Section 51476. Keeping and Availability of Records.

(a) Each provider shall keep, maintain, and have readily retrievable, such records as are necessary to fully disclose the type and extent of services provided to a Medi-Cal beneficiary. Required records shall be made at or near the time at which the service is rendered. Such records shall include, but not be limited to the following:

(7) Identification of the person rendering services. Records of each service rendered by nonphysician medical practitioners (as defined in Title 22, CCR, Section 51170) shall include the signature of the nonphysician medical practitioner and the countersignature of the supervising physician [Begin Underline]to the extent required by the applicable professional licensing statutes and regulations. [End Underline]

A similar argument applies to the addition of new language referencing "applicable professional licensing statutes and regulations" when there is no requirement for physician countersignature of services provided by an NP or a CNM in statute or regulation. Any requirement for a PA would also be covered in the Physician-Practitioner Interface. Physicians, NPs, CNMs and PAs are defined as "Providers" in 22 CCR §51051 and so every physician along with every NMP (NP, CNM and PA) is subject to the requirements of all seven (7) subsections of §51476. Certainly every provider should clearly indicate on patient records his/her identifying information. CNA respectfully suggests the following modification to Section 51476(a)(7):

(7) Identification of the person rendering services. [Begin Strikeout]~~Records of each service rendered by nonphysician medical practitioners (as defined in Title 22, CCR, Section 51170) shall include the signature of the nonphysician medical practitioner and the countersignature of the supervising physician to the extent required by the applicable professional licensing statutes and regulations.~~ [End Strikeout]

Response to Comment #2
The Department is proposing to remove requirements and/or restrictions that were placed on NMPs for participation in the Medi-Cal Program that were covered in the standards of practice established by the Medical Practice Act, Nursing Practice Act, and Physician Assistant Practice Act, which are set forth in B&P Code Sections 2000 et

seq.; 2700 et seq; and 3500 et seq., respectively and implementing regulations under Title 16, Division 2, CCR. These standards are in accordance with the authority and jurisdiction of the applicable licensing boards. The amendments proposed through this regulatory action will maintain the scope and standards of practice for Medi-Cal NMPs in the appropriate location, under each provider's applicable professional licensing statutes and regulations, as described above. This will eliminate impermissible conflict with and unnecessary duplication of provisions under the B&P Code; Title 16, CCR, Division 2; and Title 22, CCR, Division 3. This will also avoid the need to revise these regulations when the scope or standards of practice for these providers change through B&P Code and/or Title 16 changes.

Section 51476(a) pertains to the overall keeping and availability of records; paragraph (7) is designed as a subcategory of (a) specific to provider identification and signature requirements.

As proposed subsection (a)(7), includes a cross reference to applicable NMP professional licensing statutes and regulations, maintaining NMP scope and standards in the appropriate location. This cross reference includes Title 16, Division 14, Article 7*(Standardized Procedure Guidelines)*, CCR commencing with Section 1470, as specified under Section 51240(d)(1)(A) as part of the Physician-Practitioner Interface, which specifies the functions, scope and limits of NMP services.

The language proposed under subsection (a)(7) is consistent with a fundamental purpose of this regulatory proposal, which is avoiding unnecessary revisions to the regulations if the (extent/amount/scope) of standards for any of these providers is amended through the B&P Code and/or Title 16, including provisions related to the keeping and availability of records *(provider identification and signature requirements).*

The term "extent" is existing language under Sections 51305(k) and 51476(a) and is proposed under Section 51476(a)(7).
Merriam Webster's Online Dictionary defines "extent" as the point, degree or limit to which something extends; Burton's Legal Thesaurus – 3rd ed., 1998 specifies synonyms such as "scope" and "amount." As described, this term can commence at a level of "zero" or "nothing" and can increase from that point on *(i.e. if there is nothing on point, the "extent" in that scenario is zero)*. The use of this term, under Section 51476(a)(7) is appropriate and provides necessary flexibility in consideration of changing statutes and regulations.

NP and CNM providers, as well as their related professional associations have voiced considerable support for this regulatory proposal, without any noted concerns.