CALIFORNIA
HEALTH BENEFITS REVIEW PROGRAM

APPENDICES: Analysis of Assembly Bill 1214: Waiver of Benefits

CHBRP 07-09

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Waiver of Benefits

December 12, 2007

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Suggested Citation:

California Health Benefits Review Program (CHBRP). (2007). *Analysis of Assembly Bill 1214: Waiver of Benefits.* Report to California State Legislature. Oakland, CA: CHBRP. 07-09.

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APPENDIX A: TEXT OF BILL ANALYZED

BILL NUMBER: AB 1214 INTRODUCED
BILL TEXT

INTRODUCED BY Assembly Member Emmerson
(Coauthors: Assembly Members Keene, Nakanishi, and Villines)

FEBRUARY 23, 2007

An act to add Section 1367.08 to the Health and Safety Code, and to add Section 10119.3 to the Insurance Code, relating to health care coverage.

LEGISLATIVE COUNSEL'S DIGEST

AB 1214, as introduced, Emmerson. Waiver of benefits.

Existing law, the Knox-Keene Health Care Service Plan Act of 1975, provides for the licensure and regulation of health care service plans by the Department of Managed Health Care. Existing law also provides for the regulation of insurers by the Department of Insurance. Under existing law, a plan and a health insurer are required to include or offer to include specified benefits in their plan contracts or policies.

This bill would allow a health care service plan contract and a health insurance policy, on and after July 1, 2008, to be issued, renewed, or amended without certain of those specified benefits that the applicant, contractholder, or policyholder has waived. The bill would require the Director of the Department of Managed Health Care and the Insurance Commissioner to prepare a disclosure form prior to July 1, 2008, summarizing the benefits a plan and insurer are required to include in their plan contracts or policies and those that may be waived. The bill would require the applicant, contractholder, or policyholder to designate in the disclosure form the benefits he or she is waiving and to acknowledge his or her understanding, as specified, of the disclosure's contents.

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: no.

THE PEOPLE OF THE STATE OF CALIFORNIA DO ENACT AS FOLLOWS:

SECTION 1. This act shall be known, and may be cited as, The Freedom to Choose Health Benefits Act of 2007.

SEC. 2. Section 1367.08 is added to the Health and Safety Code, to read:

1367.08. (a) Notwithstanding any other provision of law, on and after July 1, 2008, a health care service plan that covers hospital, medical, or surgical expenses on an individual or group basis, may issue a plan contract that does not include one or more of the

benefits described in subdivision (b) or may amend or renew a plan contract to delete one or more of those benefits, if the applicant or the contractholder waives the benefit pursuant to subdivision (d).

(b) The benefits that may be waived pursuant to subdivision (a) are those described in Sections 1367.06, 1367.18, 1367.19, 1367.2, 1367.21, 1367.22, 1367.25, 1367.3, 1367.35, 1367.4, 1367.45, 1367.51, 1367.54, 1367.6, 1367.61, 1367.62, 1367.63, 1367.635, 1367.64, 1367.65, 1367.66, 1367.665, 1367.67, 1367.68, 1367.69, 1367.7, 1367.71, 1367.8, 1367.9, 1367.11, 1367.215, 1367.22, 1367.24, 1368.2, 1368.5, 1370.6, 1373.4, 1374.17 1374.55, 1374.56, and 1374.72.

(c) The director, in consultation with the Insurance Commissioner, shall prepare a disclosure form prior to July 1, 2008, that is easily understood and that summarizes the benefits a health care service plan is required to include in its plan contract under this chapter and the benefits that may be waived under this section.

(d) The applicant or the contractholder shall sign the disclosure described in subdivision (c), specifying the benefits he or she waives and indicating the plan has explained the contents of the disclosure and that he or she understands them before the plan contract may be issued, amended, or renewed without one or more of the benefits described in subdivision (b).

SEC. 3. Section 10119.3 is added to the Insurance Code, to read:

10119.3. (a) Notwithstanding any other provision of law, on and after July 1, 2008, a health insurance policy that covers hospital, medical, or surgical expenses on an individual or group basis, may issue a policy that does not include one or more of the benefits described in subdivision (b) or may amend or renew a policy to delete one or more of those benefits, if the applicant or policyholder waives the benefit pursuant to subdivision (d).

(b) The benefits that may be waived pursuant to subdivision (a) are those described in Sections 10119.6, 10119.8, 10119.9, 10122.1, 10123.10, 10123.141, 10123.15, 10123.18, 10123.184, 10123.185, 10123.195, 10123.196, 10123.2, 10123.21, 10123.5, 10123.55, 10123.6, 10123.7, 10123.8, 10123.81, 10123.82, 10123.83, 10123.86, 10123.87, 10123.88, 10123.89, 10123.9, 10125, 10126.6, 10127.3, 10145.2, and 10176.61.

(c) The commissioner, in consultation with the Director of the Department of Managed Health Care, shall prepare a disclosure form prior to July 1, 2008, that is easily understood and that summarizes the benefits a health insurer is required to include in its policy under this code and the benefits that may be waived under the section.

(d) The applicant or policyholder shall sign the disclosure described in subdivision (c), specifying the benefits he or she waives and indicating the insurer has explained the contents of the disclosure and that he or she understands them before the policy may be issued, amended, or renewed without one or more of the benefits described in subdivision (b).

APPENDIX B: LITERATURE REVIEW METHODS

Appendix B describes methods used in the medical effectiveness literature review for AB 1214.

AB 1214 would permit the waiver of 44 health insurance mandates and mandated offering statutes that address numerous health care services used to screen for, diagnose, treat, and manage a wide range of diseases and conditions. CHBRP reviewed evidence regarding the medical effectiveness of 31 of the 44 mandates and mandated offerings. Nine mandates were not analyzed because they do not require coverage for specific health care services or for specific diseases or conditions. Three mandates that address coverage for pharmaceuticals were not analyzed, because they apply to such a large number of diseases and conditions that the evidence is very difficult to summarize. One mandate was not analyzed because it requires coverage for vaccination against a condition for which no vaccine is currently available (i.e., the AIDS virus).

Separate literature searches were conducted for each of the mandates and mandated offerings to which AB 1214 would apply, because the health care services and diseases and conditions addressed varied so widely, as did pertinent health outcomes. Searches were initially limited to literature published during the last 10 years (1997 through 2007) to ensure that CHBRP's analysis was based on the most current evidence of effectiveness. If few studies had been published over the past decade, the searches included years prior to 1997.

Studies of the medical effectiveness of the health care services addressed in the statutes that would be subject to AB 1214 were identified through searches of the following databases: PubMed, the Cochrane Database of Systematic Reviews, the Cochrane Register of Controlled Trials, the Cumulative Index of Literature in Nursing and Allied Health, PsycInfo, the National Guideline Clearinghouse, and the International Network of Agencies for Health Technology Assessment. Web sites of organizations known to produce systematic reviews and evidence-based guidelines regarding the health care services addressed by AB 1214 were also searched. These organizations included the Agency for Healthcare Research and Quality, the Centers for Disease Control and Prevention, the National Institutes of Health, the U.S. Preventive Services Task Force, the National Health Service Centre for Reviews and Dissemination, the National Institute for Clinical Excellence, the Scottish Intercollegiate Guideline Network, the American Association of Clinical Endocrinologists, the American College of Obstetricians and Gynecologists, the American Diabetes Association, the American Psychiatric Association, and the National Comprehensive Cancer Network. In addition, previous CHBRP reports on germane topics were reviewed.

Once the literature search was completed, the strongest sources of evidence were selected for review. For this analysis, CHBRP relied primarily on meta-analyses, systematic reviews, and evidence-based practice guidelines, because these types of studies synthesize findings from multiple studies and, thus, provide the strongest evidence of effectiveness. Where multiple meta-analyses, systematic reviews, and evidence-based practice guidelines were available, CHBRP focused on the syntheses that were the most thorough and which provided the most information about the research designs of the studies synthesized. Individual studies were reviewed only if no

meta-analyses, systematic reviews, or evidence-based practice guidelines could be located, or if no such syntheses had been published recently.[1]

In making a "call" for each mandate and mandated offering to which AB 1214 would apply, the medical effectiveness team considered the number of studies as well the strength of the evidence. To grade the evidence for each outcome measured, the team used the following categories:

- Research design
- Statistical significance
- Direction of effect
- Size of effect
- Generalizability of findings

The grading system also includes an overall conclusion that encompasses findings in these categories. The conclusion is a statement that captures the strength and consistency of the evidence of an intervention's effect on an outcome. The following terms are used to characterize the body of evidence regarding an outcome:

- Clear and convincing evidence
- Preponderance of evidence
- Ambiguous/conflicting evidence
- Insufficient evidence

The conclusion states that there is "clear and convincing" evidence that an intervention has a favorable effect on an outcome, if most of the studies included in a review are well-implemented RCTs and report statistically significant and clinically meaningful findings that favor the intervention. Findings for all five grading categories listed above must be favorable in order for CHBRP to conclude that there is clear and convincing evidence of effectiveness.

The conclusion characterizes the evidence as "preponderance of evidence" that an intervention has a favorable effect if findings in most but not all five categories are favorable. For example, for some interventions the only evidence available is from nonrandomized studies or from small RCTs with weak research designs. If most such studies that assess an outcome have statistically and clinically significant findings that are in a favorable direction and enroll populations similar to those covered by a mandate, the evidence would be classified as a "preponderance of evidence favoring the intervention." In some cases, the preponderance of evidence may indicate that an intervention has no effect or an unfavorable effect.

[1] This focused approach to the literature review may have led CHBRP staff to inadvertently omit important sources of evidence from the review. However, CHBRP believes this approach is appropriate given the large number of health care services for which evidence needed to be assessed in a short period of time. In cases in which CHBRP reviewed two or more meta-analyses, systematic reviews, or evidence-based guidelines, CHBRP determined that findings were generally similar and usually differed only with regard to specific details.

The evidence is described as “ambiguous/conflicting” if none of the studies of an outcome have strong research designs and/or if their findings vary widely with regard to the direction, statistical significance, and the size of the effect.

The term “insufficient evidence” is applied when there is little if any evidence of an intervention’s effect.

Search terms used to conduct the literature searches for each statute can be made available upon request.

APPENDIX C: SUMMARY FINDINGS ON MEDICAL EFFECTIVENESS

Table C-1. Description of Studies on the Medical Effectiveness of Mandates that Could Be Waived Under AB 1214

Part A. Cancer Screening & Treatment

Topic	Citation(s)	Diagnosis	Type of Literature Review	Types of Studies Reviewed	Intervention vs. Comparison Group
Cancer screening tests	USPSTF, 2001-2004	Colorectal, bladder, lung, oral, ovarian, pancreatic, skin, and testicular cancers	Systematic review	Systematic reviews, randomized controlled trials (RCTs), nonrandomized studies with comparison groups, case series	Screening by available cancer screening tests vs. no screening
Prostate cancer screening and diagnosis	USPSTF, 2002	Prostate cancer	Systematic review	RCTs, nonrandomized studies with comparison groups	Screening by prostate-specific antigen testing and/or digital rectal examinations vs. no screening
Cervical cancer screening	USPSTF, 2003	Cervical cancer	Systematic review	Systematic reviews, RCTs, nonrandomized studies with comparison groups	Screening with conventional cervical cytology testing (Pap smears) vs. no screening Screening with conventional cervical cytology testing (Pap smears) vs. screening with new technologies to analyze cytology specimens
Mammography	USPSTF, 2002	Breast cancer	Systematic review	Meta-analyses, systematic reviews, RCTs, nonrandomized studies with comparison groups	Mammography screening vs. usual care

Topic	Citation(s)	Diagnosis	Type of Literature Review	Types of Studies Reviewed	Intervention vs. Comparison Group
Breast cancer screening, diagnosis, and treatment	ICSI, 2005 NCCN, 2007 USPSTF, 2002	Breast cancer	Systematic review	Meta-analyses, RCTs, nonrandomized studies with comparison groups, case series, guidelines based on consensus or expert opinion	Screening vs. usual care Treatment vs. usual care Treatment vs. placebo or alternative treatment For diagnostic procedures, intervention and comparison groups were not clearly defined
Mastectomy and lymph node dissection – length of stay	CHBRP, 2005a	Breast cancer	Systematic review	Nonrandomized studies with comparison groups, case series	Outpatient mastectomy vs. inpatient mastectomy

Part B. Chronic Conditions

Topic	Citation(s)	Diagnosis	Type of Literature Review	Types of Studies Reviewed	Intervention vs. Comparison Group
Diabetes management	AACE, 2007 ACOG, 2001 ADA, 2006	Type 1 diabetes, Type 2 diabetes, and gestational diabetes	Systematic review	Meta-analyses, RCTs, nonrandomized studies with comparison groups, guidelines based on consensus or expert opinion	Treatment vs. no treatment Treatment vs. alternative treatment
Osteoporosis	ICSI, 2006 SIGN, 2003	Osteoporosis	Systematic review	Meta-analyses, RCTs, nonrandomized studies with comparison groups, case series, guidelines based on consensus or expert opinion	Intervention and comparison groups were not clearly defined

Topic	Citation(s)	Diagnosis	Type of Literature Review	Types of Studies Reviewed	Intervention vs. Comparison Group
Transplantation services for persons with HIV	CHBRP, 2005b	Diseases requiring organ transplants	Systematic review	Case series, case reports	N/A: all subjects underwent transplantation services
Phenyl-ketonuria – medical formula and medical foods	NIH, 2000 Fernandes et al., 2006 Nyhan et al., 2005	Phenylketonuria	Evidence-based guideline Narrative review Narrative review	Case series, case studies	N/A: all subjects were screened for phenylketonuria or received medical formula and medical foods

Part C. Mental Illness and Substance Abuse

Topic	Citation(s)	Diagnosis	Type of Literature Review	Types of Studies Reviewed	Intervention vs. Comparison Group
Parity in coverage for severe mental illness[2] and coverage for mental and nervous disorders	APA, 2002 NCCMH, 2006	Bipolar disorder	Systematic review	RCTs, nonrandomized studies with comparison groups, case series	Medication vs. placebo Medication vs. electroconvulsive therapy (ECT) Medication vs. medication plus psychotherapy Medication vs. medication plus ECT

[2] Due to the limited time available to complete this report, the review of the evidence regarding the effectiveness of treatment for mental illness focused on three of the most severe mental illnesses: bipolar disorder, major depressive disorder, and schizophrenia.

Topic	Citation(s)	Diagnosis	Type of Literature Review	Types of Studies Reviewed	Intervention vs. Comparison Group
	APA, 2000 NCCMH, 2004	Major depressive disorder	Systematic review	Meta-analyses, systematic reviews, RCTs, nonrandomized studies with comparison groups	Medication vs. placebo Medication vs. psychotherapy Medication vs. medication and psychotherapy Medication vs. medication plus ECT Psychotherapy vs. no treatment Psychotherapy vs. psychotherapy and medication ECT vs. placebo ECT vs. medication Light therapy vs. other treatments Medication or psychotherapy vs. medication or psychotherapy plus light therapy

Topic	Citation(s)	Diagnosis	Type of Literature Review	Types of Studies Reviewed	Intervention vs. Comparison Group
	APA, 2000 NCCMH, 2003	Schizophrenia	Systematic review	Meta-analyses, systematic reviews, RCTs, nonrandomized studies with comparison groups, time series, case series, case reports, textbooks, expert opinion	Antipsychotic medication vs. placebo First-generation antipsychotic medication vs. second-generation antipsychotic medication Antipsychotic medication vs. antipsychotic medication plus other types of medication ECT vs. sham ECT ECT vs. antipsychotic medication ECT plus antipsychotic medication vs. antipsychotic medication
Alcoholism Treatment	APA, 2006 Mann et al., 2004 Srisurapanont et al., 2007	Alcoholism	Systematic review Meta-analysis Meta-analysis	Meta-analyses, RCTs, nonrandomized studies with comparison groups, case series, guidelines based on consensus or expert opinion.	**For pharmacologic studies:** Medication vs. placebo Medication A vs. Medication B Medication plus psychosocial therapy vs. psychosocial therapy **For psychosocial treatments (as primary treatment) and treatment settings:** Intervention and comparison groups were not clearly defined

Part D. Orthotics and Prosthetics

Topic	Citation(s)	Diagnosis	Type of Literature Review	Types of Studies Reviewed	Intervention vs. Comparison Group
Orthotics and prosthetics	CHBRP, 2006	Multiple diagnoses	Systematic review	Meta-analyses, systematic reviews, RCTs, case series	Comparisons of two or more types of prosthetic devices
	McLauchlan and Handoll, 2001	Achilles tendonitis	Systematic review	RCTs, nonrandomized studies with comparison groups	Heel pads vs. no treatment
	Ferrari et al., 2004	Deviation of the big toe and bunions	Systematic review	RCTs, nonrandomized studies with comparison groups	Foot splints vs. no treatment Insoles vs. no treatment
	Brouwer et al., 2005	Osteoarthritis	Systematic review	RCTs, nonrandomized studies with comparison groups	Knee brace vs. neoprene sleeve vs. no treatment
	D'hondt et al., 2002	Patellofemoral pain syndrome	Systematic review	RCTs, nonrandomized studies with comparison groups	Knee brace vs. no treatment
	Crawford and Thomson, 2003	Plantar heel pain	Systematic review	RCTs, nonrandomized studies with comparison groups	Heel pads vs. no treatment Insoles vs. no treatment
	Clark et al., 2006 Egan et al., 2003	Rheumatoid arthritis	Systematic review	Systematic reviews, RCTs, nonrandomized studies with comparison groups	Foot orthoses vs. no treatment Hand splints vs. no treatment Wrist splints vs. no treatment

Topic	Citation(s)	Diagnosis	Type of Literature Review	Types of Studies Reviewed	Intervention vs. Comparison Group
	Handoll et al., 2001 Yeung and Yeung, 2001	Sprains and strains	Meta-analysis Systematic review	RCTs, nonrandomized studies with comparison groups	Air-cast ankle brace vs. no treatment Semi-rigid ankle orthosis vs. no treatment Insoles vs. no treatment Knee brace vs. no treatment
	Rome et al., 2005	Stress fractures	Systematic review	RCTs, nonrandomized studies with comparison groups	Boot inserts vs. no treatment Leg brace vs. no treatment
Prosthetic devices for persons who have had a laryngectomy	Arias et al., 2000 Carr et al., 2000 Evitts and Searl, 2006 Farrand and Duncan, 2007 Globlek et al., 2004 Stajner-Katusic et al., 2004 Tsai et al., 2002	Cancer of the larynx Severe injury to the larynx	No literature reviews were located – relied on individual studies	Nonrandomized studies with comparison groups	Tracheoesophageal speech with voice prosthesis[3] vs. normal speech Tracheoesophageal speech with voice prosthesis vs. esophageal speech vs. electrolaryngeal speech

[3] Persons who have a laryngectomy lose the ability to speak normally. The three methods most frequently used to enable persons with laryngectomies to speak are esophageal speech, electrolaryngeal speech, and tracheosophageal speech with voice prosthesis. Esophageal speech involves the use of the esophagus to produce sound in place of the larynx. Tracheoesophageal speech is generated through use of a one-way valve that is placed in an incision in the wall between the esophagus and the trachea. This prosthesis allows air from the lungs to flow into the esophagus to produce sound and prevents food and liquid from entering the

Topic	Citation(s)	Diagnosis	Type of Literature Review	Types of Studies Reviewed	Intervention vs. Comparison Group
Special footwear for persons suffering from foot disfigure-ment	Maciejewski et al., 2004 McIntosh, et al., 2003	Diabetes	Systematic review Systematic review	RCTs, nonrandomized studies with comparison groups, time series	Therapeutic shoes vs. conventional footwear Therapeutic shoes with orthoses vs. conventional footwear Therapeutic shoes vs. total contact cast vs. diabetic walker
	Farrow et al., 2005	Rheumatoid arthritis	Systematic review	RCTs, controlled clinical trials, case series	Therapeutic shoes vs. conventional footwear Therapeutic shoes with orthoses vs. therapeutic shoes alone

lungs from the trachea. Electrolarygneal speech is produced by a battery-operated machine that is held against the neck or placed in a small tube in the corner of the mouth. Speech therapy and practice are needed to successfully use any of these three methods.

Part E. Pain Management

Topic	Citation(s)	Diagnosis	Type of Literature Review	Types of Studies Reviewed	Intervention vs. Comparison Group
Acupuncture	CHBRP, 2007b	Multiple diagnoses	Systematic review	Meta-analyses, systematic reviews, RCTs	Acupuncture vs. no treatment Acupuncture vs. sham acupuncture Acupuncture vs. other treatment Acupuncture adjuvant to other treatment vs. other treatment
Pain management medication for persons with terminal illnesses	AHRQ, 2001	Multiple diagnoses	Systematic review	RCTs, nonrandomized studies with comparison groups	Prescription drug vs. placebo Nonsteroidal anti-inflammatory drugs (NSAIDs) vs. opioids NSAIDs vs. NSAIDs plus "weak" opioids[4] Opioids vs. opioids plus other types of medications
General anesthesia for dental procedures	SIGN, 2004 AAP and AAPD, 2006 ADA, 2005	Dental Conditions	Evidence-based guideline Guideline based on consensus Guideline based on consensus	Nonrandomized studies with comparison groups, case series, case reports, expert opinion	Intervention and comparison groups were not clearly defined

[4] "Weak" opioids are opioids that are typically prescribed to relieve mild or moderate pain.

Part F. Pediatric Health

Topic	Citation(s)	Type of Service	Type of Literature Review	Types of Studies Reviewed	Intervention vs. Comparison Group
Comprehensive preventive care for children aged 16 years or younger Comprehensive preventive care for adolescents aged 17 and 18 years	USPSTF, 1996 CDC growth charts for the United States; National Center for Health Statistics, 2000	Measurement: Height, weight, blood pressure, head circumference	Guidelines based on consensus or expert opinion	Not applicable	Not applicable
	USPSTF, 2006	Hearing screening: newborns	Systematic review	Nonrandomized studies with comparison groups, case series	Neonatal screening vs. usual care
	Recommendations for Preventive Pediatric Health Care, AAP, 2000	Hearing screening: 3-16 years	Guidelines based on consensus or expert opinion	Not applicable	Not applicable
	USPSTF, 2004	Visual impairment screening	Systematic review	RCTs	Intensive visual-screening vs. usual visual screening care
	Recommendations for Preventive Pediatric Health Care, AAP, 2000	Routine developmental/ behavioral assessments	Guidelines based on consensus or expert opinion	Not applicable	Not applicable
	Recommendations for Preventive Pediatric Health Care, AAP, 2000	Periodic physical examinations	Guidelines based on consensus or expert opinion	Not applicable	Not applicable
	USPSTF, 1996	Metabolic disorders: newborn screening	Systematic review	Not reported	Not reported

Topic	Citation(s)	Type of Service	Type of Literature Review	Types of Studies Reviewed	Intervention vs. Comparison Group
	USPSTF, 2006	Screening for iron deficiency anemia in children aged 6 months through 12 months	Systematic review	Longitudinal studies, time series	Anemia Screening – no comparison group
	Recommendations for Preventive Pediatric Health Care, AAP, 2000	Screening for iron deficiency anemia among high risk infants Aged 15 months through 5 years	Guidelines based on consensus or expert opinion	Not applicable	Not applicable
	Recommendations for Preventive Pediatric Health Care, AAP, 2000	Urinalysis	Guidelines based on consensus or expert opinion	Not applicable	Not applicable
	USPSTF, 2006	Screening for blood lead levels	Systematic review	Meta-analyses, RCTs, nonrandomized studies with comparison groups	Screening by blood lead testing vs. no screening
	Recommendations for Preventive Pediatric Health Care, AAP, 2000	Tuberculin testing	Guidelines based on consensus or expert opinion	Not applicable	Not applicable
	Recommendations for Preventive Pediatric Health Care, AAP, 2000	Cholesterol screening	Guidelines based on consensus or expert opinion	Not applicable	Not applicable
	USPSTF, 2004-2007	Sexually transmitted disease screening	Systematic review	Tests of the sensitivity of screening tests	Screening by newly available tests vs. standard screening tests
	USPSTF, 1996	Counseling parents and children regarding nutrition, injury prevention, and violence prevention	Systematic review	RCTs, nonrandomized studies with comparison groups	Specialized dietary counseling vs. usual physician care Clinical counseling on injury prevention vs. no counseling

Topic	Citation(s)	Type of Service	Type of Literature Review	Types of Studies Reviewed	Intervention vs. Comparison Group
	Recommendations for Preventive Pediatric Health Care, AAP, 2000	Counseling parents regarding infant sleeping position	Guidelines based on consensus or expert opinion	Not applicable	Not applicable
	Recommendations for Preventive Pediatric Health Care, AAP, 2000	Periodic dental examinations	Guidelines based on consensus or expert opinion	Not applicable	Not applicable
	USPSTF, 1996	Diphtheria and tetanus toxoids and acellular pertussis vaccine	Systematic review	RCTs, nonrandomized studies with comparison groups, time series, case series, case reports	Vaccine vs. no vaccine Vaccine with acellular form of pertussis vs. vaccine with whole-cell form of pertussis
	USPSTF, 1996	Haemophilus influenza type B conjugate vaccine	Systematic review	RCTs, nonrandomized studies with comparison groups, time series, case series	Vaccine vs. placebo Vaccine vs. no vaccine
	USPSTF, 1996	Hepatitis A vaccine	Systematic review	RCTs, time series, case series	Vaccine vs. placebo Vaccine vs. no vaccine
	USPSTF, 1996	Hepatitis B vaccine	Systematic review	RCTs, cluster RCTs, nonrandomized studies with comparison groups, time series, case series	Vaccine vs. placebo Vaccine vs. no vaccine Vaccine alone vs. vaccine plus hepatitis B immunoglobulin
	CHBRP, 2007	Human papillomavirus vaccine	Systematic review	RCTs	Vaccine vs. placebo

Topic	Citation(s)	Type of Service	Type of Literature Review	Types of Studies Reviewed	Intervention vs. Comparison Group
	CDC ACIP, 2000 USPSTF, 1996	Inactivated poliovirus vaccine	Systematic review	RCTs, nonrandomized studies with comparison groups, time series, case series	Vaccine vs. no vaccine Inactivated poliovirus vaccine vs. oral poliovirus vaccine vs. combination of doses of inactivated and oral poliovirus vaccine
	USPSTF, 1996	Influenza vaccine	Systematic review	RCTs, nonrandomized studies with comparison groups, case series	Vaccine vs. placebo Vaccine vs. no vaccine
	USPSTF, 1996	Measles, mumps, and rubella vaccine	Systematic review	Nonrandomized studies with comparison groups, time series, case series	Vaccine vs. no vaccine
	CDC, 2005c	Meningococcal polysaccharide vaccine (MPSV4)	Narrative review	RCTs, nonrandomized studies with comparison groups, time series, case series	Vaccine vs. no vaccine Repeat vaccination with MPSV4 vs. vaccination with both MPSV4 and MCV4
	CDC, 2005c	Meningococcal conjugant vaccine (MCV4)	Narrative review	RCTs, nonrandomized studies with comparison groups	Vaccine vs. no vaccine MPSV4 vs. MCV4
	USPSTF, 1996	Pneumococcal polysaccharide vaccine	Systematic review	Meta-analysis, RCTs, nonrandomized studies with comparison groups	Vaccine vs. placebo Vaccine vs. no vaccine
	CDC, 2006	Rotavirus vaccine	Narrative review	RCTs	Vaccine vs. placebo

Topic	Citation(s)	Type of Service	Type of Literature Review	Types of Studies Reviewed	Intervention vs. Comparison Group
	USPSTF, 1996	Tetanus and diphtheria toxoids and acellular pertussis vaccine (TDaP)	Systematic review	RCTs, nonrandomized studies with comparison groups, time series, case series, case reports	Vaccine vs. no vaccine Vaccine with acellular form of pertussis vs. vaccine with whole-cell form of pertussis
	USPSTF, 1996	Varicella vaccine	Systematic review	RCTs, nonrandomized studies with comparison groups, time series, case series	Vaccine vs. placebo Vaccine vs. no vaccine
Asthma management	CHBRP, 2004 CHBRP, 2006a NHLBI, 2007	Asthma	Systematic review Systematic review Evidence-based guideline	Meta-analyses, systematic reviews, RCTs, nonrandomized studies, case series	Peak flow meter vs. symptom monitoring Metered dose inhaler (MDI) with spacer vs. MDI without spacer Nebulizer vs. inhaler Asthma education vs. usual care
Screening children for blood lead levels	USPSTF, 2006	Lead poisoning	Systematic review	Meta-analyses, RCTs, nonrandomized studies with comparison groups	Screening by blood lead testing vs. no screening

Part G. Reproductive Health

Topic	Citation(s)	Diagnosis	Type of Literature Review	Types of Studies Reviewed	Intervention vs. Comparison Group
Contraceptive devices requiring a prescription	WHO, 2004	Pregnancy	Systematic review	RCTs, nonrandomized studies with comparison groups, time series, case series, case reports	Prescription contraceptives[5] vs. no method of contraception Prescription contraceptives vs. non-prescription contraceptives[6] Barrier methods of contraception vs. intrauterine devices (IUDs) vs. hormone-based methods
Infertility Treatments	Attia et al., 2007 Luttjeboer et al., 2007 NCCWCH, 2004	Infertility	Systematic review	Meta-analyses, RCTs, nonrandomized studies with comparison groups, case series, guidelines based on consensus or expert opinion	Intervention and comparison groups were not clearly defined
Prenatal diagnosis of genetic disorders	ACOG Committee on Practice Bulletins, 2007 Alfirevic et al., 2003	Genetic abnormalities of fetus	Systematic review	RCTs, guidelines based on consensus or expert opinion	Diagnostic testing for genetic disorders by chorionic villus sampling vs. second trimester amniocentesis

[5] Prescription contraceptives can be divided into three major categories. Barrier methods are devices inserted into the vagina that are used in conjunction with a spermicide and removed between episodes of intercourse. They include the cervical cap, the cervical shield, and the diaphragm. Intrauterine devices are small devices composed of copper wire wrapped around a plastic frame that are implanted in the uterus. Hormone-based contraceptives prevent ovulation and change the lining of the uterus and cervical mucus to prevent pregnancy. Multiple methods have been developed to deliver hormone-based contraceptives, including pills, injections, implants, skin patches, and vaginal rings.

[6] Non-prescription methods of contraception include condoms, spermicides, periodic abstinence, and withdrawal.

Expanded alpha-fetoprotein testing	ACOG Committee on Practice Bulletins, 2007	Down syndrome	Systematic review	RCTs, nonrandomized studies with comparison groups, guidelines based on consensus or expert opinion	Screening for Down syndrome: first-trimester screening vs. second-trimester screening.

Part H. Surgical

Topic	Citation(s)	Diagnosis	Type of Literature Review	Types of Studies Reviewed	Intervention vs. Comparison Group
Jawbone or associated bone joints – surgery	Reston and Turkelson, 2003	Temporo mandibular joint disorder	Meta-analysis[7]	Case series	Surgery vs. no treatment
Reconstructive surgery	Fung et al., 2001 Holly et al., 2003 Janz et al., 2005 Nano et al., 2005 Nissen et al., 2001 Pusic et al., 1999 Rowland et al., 2000 Rubino et al., 2006 Yurek et al., 2000	Breast cancer	No literature reviews were located – relied on individual studies	Nonrandomized studies with comparison groups	Mastectomy with breast reconstruction vs. mastectomy alone Mastectomy with breast reconstruction vs. breast-conserving therapy Breast-conserving therapy vs. mastectomy alone

[7] Meta-analyses usually synthesize results from RCTs. In this study, the authors combined published estimates of outcomes in untreated patients with published estimates of outcomes reported in case series studies of surgical treatments for temporomandibular joint disorders. This is a novel method for combining results of studies in areas of health care in which RCTs are typically not conducted.

Topic	Citation(s)	Diagnosis	Type of Literature Review	Types of Studies Reviewed	Intervention vs. Comparison Group
	Roye et al., 2001 Vitale, et al., 2005	Clubfoot	No literature reviews were located – relied on individual studies	Nonrandomized studies with comparison groups, case series	Young adults who have had surgical treatment for clubfoot vs. young adults with healthy feet
	Endriga and Kapp-Simon, 1999 Marcusson et al., 2001 Marcusson et al., 2002 Sarwer et al., 1999	Craniofacial abnormalities	Narrative review[8]	Nonrandomized studies with comparison groups, case series	Persons with craniofacial abnormalities vs. persons without facial disfigurement

Part I. Other

Topic	Citation(s)	Diagnosis	Type of Literature Review	Types of Studies Reviewed	Intervention vs. Comparison Group
Hospice care	Harding et al., 2005 Higginson et al., 2003 NICE 2004	Multiple diagnoses	Systematic review	RCTs, nonrandomized studies with comparison groups, case series	Home-based hospice care vs. usual care Inpatient hospice care vs. usual care Home-based and inpatient hospice care vs. usual care

[8] The narrative review by Endriga and Kapp-Simon (1999) did not include the three individual studies cited.

Topic	Citation(s)	Diagnosis	Type of Literature Review	Types of Studies Reviewed	Intervention vs. Comparison Group
Home health care	Hedrick et al., 1989 Hughes et al., 1997 Parker et al., 2002	Multiple diagnoses	Meta-analysis Meta-analysis Systematic review	RCTs, nonrandomized studies with comparison groups	Home care vs. usual care
	Parker et al., 2002	Very low birth weight	Systematic review	RCTs, nonrandomized studies with comparison groups	Home care vs. usual care
	Parker et al., 2002	Asthma or diabetes	Systematic review	RCTs, nonrandomized studies with comparison groups	Home care vs. usual care
	Cunliffe et al., 2004 Shepperd and Iliffe, 2005	Multiple diagnoses	N/A[9] Meta-analysis	RCTs	Home-based rehabilitation care vs. inpatient rehabilitation care
	Crotty et al., 2002 Giusti et al., 2006 Kuisma 2002	Hip fracture	No literature reviews were located – relied on individual studies	RCT Nonrandomized study with comparison group RCT	Home-based rehabilitation care vs. inpatient rehabilitation care

[9] Cunliffe and colleagues (2004) is an individual study published after the studies synthesized in Shepperd and Iliffe's (2005) meta-analysis.

Topic	Citation(s)	Diagnosis	Type of Literature Review	Types of Studies Reviewed	Intervention vs. Comparison Group
	Early Supported Discharge Trialists, 2005 Langhorne et al., 2007	Stroke	Meta-analysis	RCTs	Home-based rehabilitation care vs. inpatient rehabilitation care

Legend for Sources of Evidence:

AACE = American Association of Clinical Endocrinologists**,** AAP = American Academy of Pediatrics, AAPD = American Academy of Pediatric Dentistry, ACOG = American College of Obstetricians and Gynecologists, ADA = American Diabetes Association, ADA = American Dental Association, AHRQ = Agency for Healthcare Research and Quality, APA = American Psychiatric Association, CDC ACIP = Centers for Disease Control and Prevention Advisory Committee on Immunization Practices, CHBRP = California Health Benefits Review Program, ICSI = Institute for Clinical Systems Improvement, NCCMH = National Collaborating Centre for Mental Health, NCCN = National Comprehensive Cancer Network, Inc., NCCWCH = British National Collaborating Centre for Women's and Children's Health, NHLBI = National Heart, Lung, and Blood Institute, NICE = National Institute for Clinical Excellence, NIH = National Institutes of Health, SIGN = Scottish Intercollegiate Guidelines Network, USPSTF = US Preventive Services Task Force, WHO = World Health Organization.

Table C-2. Description of Studies on the Medical Effectiveness of Mandates that Could Be Waived Under AB 1214

Part A. Cancer Screening and Treatment

Topic	Citation(s)	Diagnosis	Conclusion
Cancer screening tests **Prostrate cancer screening, cervical cancer screening, and mammography are discussed elsewhere in sections regarding mandates for coverage of these specific tests.	USPSTF, 2001-2004	Colorectal cancer	**All types of colorectal cancer screening vs. no screening:** There is a *preponderance of evidence* that several screening methods for colorectal cancer screening are *effective* in reducing mortality from colorectal cancer. A *preponderance of evidence* suggests that the benefits from screening for colorectal cancer substantially outweigh potential harms. **Fecal Occult Blood Testing (FOBT) vs. no screening:** There is *clear and convincing evidence* that periodic screening with FOBT alone reduces mortality from colorectal cancer. **Sigmoidoscopy vs. no screening:** There is a *preponderance of evidence* that screening with sigmoidoscopy alone reduces mortality from colorectal cancer. **Sigmoidoscopy in conjunction with FOBT vs. no screening:** There is a *preponderance of evidence* that screening with FOBT in conjunction with sigmoidoscopy is more effective than screening with either alone in reducing mortality from colorectal cancer. **Screening colonoscopy vs. no screening:** There is a *preponderance of evidence* that screening with colonoscopy is effective in reducing colorectal cancer mortality. However, colonoscopy is a more invasive procedure than FOBT and sigmoidoscopy. Colonoscopy is also usually performed under sedation, which requires support personnel with expertise in airway management.

Topic	Citation(s)	Diagnosis	Conclusion
		Bladder cancer	**Screening by available bladder cancer screening tests vs. no screening:** There is a *preponderance of evidence* that screening with available tests can detect bladder cancer in asymptomatic individuals. There is *insufficient evidence* that early treatment of bladder cancer detected through screening improves long-term health outcomes, because there is *insufficient evid*ence that the majority of asymptomatic cases of bladder cancer detected by screening would progress to clinically significant disease. A *preponderance of evidence* suggests that the potential harms of screening for bladder cancer, such as false positive test results and invasive procedures, outweigh any potential benefits.
		Lung cancer	**Screening with chest X-ray and/or sputum cytology and/or low-dose computerized tomography (LDCT) vs. no screening:** There is a *preponderance of evidence* that screening with chest X-ray, sputum cytology, and/or low-dose computerized tomography (LDCT) can detect lung cancer at an earlier stage than would be detected in an unscreened population. There is *insufficient evidence* that screening strategies for lung cancer reduce mortality from lung cancer. Due to the nature of the invasive procedures in diagnostic testing for lung cancer and the high number of false positive screen results, there is *insufficient evidence* to determine whether the benefits of screening outweigh the harms.
		Oral cancer	**Screening by oral inspection vs. no screening:** There is *insufficient evidence* that screening for oral cancer improves health outcomes for either high-risk adults (i.e., those over the age of 50 who use tobacco) or for average-risk adults in the general population. There is *insufficient evidence* for the harms of oral cancer screening but it is questionable if the benefits of screening outweigh the harms.

Topic	Citation(s)	Diagnosis	Conclusion
		Ovarian cancer	**Screening with serum CA-125 tests and/ or transvaginal ultrasound tests vs. usual care:** There is a *preponderance of evidence* that screening asymptomatic, average-risk females with ultrasound or with CA-125 tests followed by ultrasound can detect ovarian cancer at an earlier stage than would be detected in the absence of screening. There is *insufficient evidence* that earlier detection of ovarian cancer has a significant effect on mortality from ovarian cancer. Because ovarian cancer is relatively rare in the general population and diagnostic testing after a positive screen is invasive, there is a *preponderance of evidence* that screening for ovarian cancer may pose harms that would outweigh any potential benefits of screening.
		Pancreatic cancer	**Screening vs. no screening:** There is *insufficient evidence* that screening for pancreatic cancer is effective in reducing mortality. Due to the low prevalence of pancreatic cancer, the limited accuracy of available screening tests, the invasive nature of diagnostic tests, and poor treatment outcomes for pancreatic cancer, the harms of screening likely exceed any potential benefits.
		Skin cancer	**Skin examination by clinicians vs. no screening:** There is *insufficient evidence* that skin examination by clinicians is effective in reducing mortality or disease burden caused by skin cancer. There is *insufficient evidence* to determine whether the benefits outweigh the harms of periodic skin examination.

Topic	Citation(s)	Diagnosis	Conclusion
		Testicular cancer	**Clinical examination or testicular self-examination vs. no screening:** There is *insufficient evidence* that testicular cancer screening is effective in reducing mortality from testicular cancer. In the absence of screening, treatment outcomes for testicular cancer are highly favorable. Due to the low prevalence of testicular cancer, the limited accuracy of screening tests, and *insufficient evidence* for the incremental benefits of screening, there is no consensus that benefits of screening would outweigh potential harms.
Prostate cancer screening and diagnosis	USPSTF, 2002	Prostate cancer	**Screening by prostate specific antigen (PSA) testing and/or digital rectal examination (DRE) vs. no screening:** There is a *preponderance of evidence* that prostate cancer screening can effectively detect prostate cancer in its early stages, either using PSA or DRE. There is *insufficient evidence* to determine whether early detection of prostate cancer improves health outcomes. For many males, the benefits of early detection and treatment may not outweigh the harms because many of the cancers detected may never affect their health. Harms of screening include false positive test results, which can lead to unnecessary biopsies, treatments, and complications. If prostate cancer screening were to improve health outcomes, the population most likely to benefit would be those aged 50 to 70 years. PSA is more sensitive at detecting prostate cancer than DRE.

Topic	Citation(s)	Diagnosis	Conclusion
Cervical cancer screening	USPSTF, 2003	Cervical cancer	**Screening with conventional cervical cytology testing (Pap smears) vs. no screening:** There is a *preponderance of evidence* that routine screening with Pap smears can effectively reduce the incidence of and mortality from cervical cancer. Evidence to determine an optimal age to begin and an appropriate age to stop screening for cervical cancer is limited. Indirect evidence suggests that the most beneficial period to begin screening for cervical cancer is within 3 years of onset of sexual activity or at age 21. The most favorable interval for routine screening is within the range of up to every 3 years. There is a *preponderance of evidence* that screening females older than 65 years may pose risk for potential harms. These potential harms, such as false positive test results and invasive procedures, exceed benefits among females who have previously had normal screening results and who are not at high risk for cervical cancer. **Screening with Pap smears vs. screening with new technologies to analyze cytology specimens:** There is *insufficient evidence* to recommend for or against the routine use of new technologies to screen for cervical cancer in the place of conventional Pap smears.

Topic	Citation(s)	Diagnosis	Conclusion
Mammography	USPSTF, 2002	Breast cancer	There is a *preponderance of evidence* to determine that mammography screening every 12 to 33 months significantly reduces mortality from breast cancer. The evidence for mammography screening and risk reduction for breast cancer mortality is strongest for females aged 50 through 69 years. The evidence that mammography screening reduces mortality risk from breast cancer for females aged 40 through 49 years is less certain than the evidence of the benefits of screening for those aged 50 through 69 years. Possible factors that contribute to the varying effectiveness of breast cancer screening with mammography include an individual's hormonal equilibrium, breast density, and age. There is *insufficient evidence* that mammography screening is beneficial for those females older than 74 years, due to lack of studies. The likelihood of harms from mammography, screening such as false positive test results, biopsies, and unnecessary anxiety, diminish from ages 40 through 70 years. There is *insufficient evidence* that performing a clinical breast exam in conjunction with mammography contributes to a reduction in mortality risk from breast cancer.
Breast cancer screening, diagnosis, and treatment	ICSI, 2005 NCCN, 2007 USPSTF, 2002	Breast cancer	**Screening** There is *clear and convincing evidence* that routine mammography screening significantly reduces mortality from breast cancer. Additional evidence for mammography screening is discussed elsewhere in the section on mammography. There is *insufficient evidence* to recommend for or against performing clinical breast examination in conjunction with mammography or as a stand-alone screening procedure.

Topic	Citation(s)	Diagnosis	Conclusion
			There is *insufficient evidence* to recommend for or against teaching or performing routine breast self-examination. There is *insufficient evidence* to recommend the routine use of breast scintigraphy or ductal lavage as breast cancer screening procedures. There is *insufficient evidence* to recommend the routine use of breast magnetic resonance imaging (MRI) as a screening procedure in average risk females. There is *insufficient evidence* to support the use of MRI for breast cancer screening as an adjunct to mammography for high risk females. There is *insufficient evidence* to support the use of ultrasound for breast cancer screening as an adjunct to mammography for high risk females or females with dense breast tissue. **Diagnostic Testing** There is a *preponderance of evidence* that for those females who have breast tissue suspicious or highly suggestive of malignancy, core needle biopsy or aspiration should be performed. Needle localization excisional biopsy with specimen radiograph is recommended as an alternative procedure if core needle biopsy (preferred) is not available. **Treatment** **Surgery:** There is *clear and convincing evidence* that modified radical mastectomy and breast-conserving therapy (lumpectomy with levels I and II axillary node dissection, plus radiotherapy) are equally effective primary treatments for most females with stage I and stage II breast cancer. It is recommended that females who are eligible for breast conserving surgery

Topic	Citation(s)	Diagnosis	Conclusion
			be offered the choice of either breast-conserving therapy or modified radical mastectomy.[10] There is a *preponderance of evidence* to recommend total mastectomy and further systemic chemotherapy or hormone therapy treatment for females who have been diagnosed as having stage III (inoperable locally advanced breast cancer) disease or stage IV (metastatic or recurrent breast cancer) disease upon clinical examination. Evidence regarding the effects of breast reconstruction surgery following mastectomy is addressed elsewhere in the section on reconstructive surgery. **Hormone Therapy**: There is a *preponderance of evidence* to recommend preoperative hormone therapy in the treatment of postmenopausal females with hormone receptor-positive breast cancer disease. There is a *preponderance of evidence* that postoperative hormone therapy (e.g., tamoxifen, raloxifene) reduces risk of invasive breast cancer among females with lobular carcinoma in situ (LCIS). There is *clear and convincing evidence* to recommend postoperative tamoxifen therapy treatment to females with ductal carcinoma in situ (DCIS) who undergo breast-conserving therapy. There is a *preponderance of evidence* to recommend tamoxifen therapy treatment to females with DCIS who undergo mastectomy. There is a *preponderance of evidence* that prolonged tamoxifen therapy (five or more years) reduces the likelihood of recurring invasive breast cancer when administered to females with estrogen-receptor positive or receptor-unknown

[10] Breast-conserving therapy is contraindicated for patients who have received previous moderate or high-dose radiotherapy to the breast or chest wall, are pregnant and would require radiotherapy during pregnancy, have suspicious or malignant-appearing microcalcifications on mammography, or have widespread disease that cannot be treated by local excision.

Topic	Citation(s)	Diagnosis	Conclusion
			invasive tumors. There is a *preponderance of evidence* to recommend that females with invasive breast cancers that are estrogen or progesterone receptor positive be considered for adjuvant hormone therapy regardless of patient age, lymph node status, or if adjuvant chemotherapy is to be administered. There is a *preponderance of evidence* to recommend the use of minimally toxic hormone therapies vs. chemotherapy whenever medically indicated in treating females with systemic recurrence of breast cancer. **Chemotherapy:** There is *clear and convincing evidence* that adjuvant chemotherapy confers an overall survival advantage to the patient. For individual patients, the choice of chemotherapy must be based on balancing the expected improvement in survival and the patient's willingness to accept the side effects of treatment. There is a *preponderance of evidence* that preoperative chemotherapy be considered for females with large clinical stage II tumors who meet the criteria for breast-conserving therapy and who wish to undergo it instead of mastectomy. There is *clear and convincing evidence* that patients with lymph node involvement or with tumors greater than 1 cm in diameter be considered for chemotherapy or hormone therapy or a combination thereof. There is *clear and convincing evidence* to recommend chemotherapy to females with lymph node-negative, hormone receptor-negative tumors greater than 1 cm in diameter. There is *clear and convincing evidence* to recommend hormone therapy in addition to chemotherapy for females with lymph node-negative, hormone receptor-positive breast cancer tumors greater than 1 cm in diameter.

Topic	Citation(s)	Diagnosis	Conclusion
			Radiation Therapy: There is *a preponderance of evidence* to recommend that chest wall and regional lymph node irradiation be performed in females with positive axillary lymph nodes after mastectomy and axillary lymph node dissection. There is *clear and convincing evidence* to recommend whole breast irradiation after breast-conserving surgery to reduce the risk of in-breast disease recurrence. **Immune Therapy:** There is *clear and convincing evidence* that immune therapy can significantly improve disease-free survival in patients with high-risk, HER2-positive breast cancer.
Mastectomy and lymph node dissection – length of stay	CHBRP, 2005a ICSI, 2005 NCCN, 2007	Breast cancer	No guidelines specifying a recommended length of stay for mastectomy or lymph node dissection could be located. Most evidence regarding length of stay for these procedures comes from studies that compare their provision on an inpatient versus an outpatient basis. A *preponderance of evidence* suggests that infection control, pain control, and physical and psychological recovery from surgery are *similar or better* for females who have mastectomies on an outpatient basis than for females who have inpatient mastectomies. There is *insufficient evidence* to determine whether other important outcomes, such as hospital readmission and postoperative bleeding, are similar for outpatient and inpatient mastectomies. Evidence regarding the impact of breast reconstruction following mastectomy is discussed elsewhere in the section on the reconstructive surgery mandate.

Part B. Chronic Conditions

Topic	Citation(s)	Diagnosis	Conclusion
Diabetes management and treatment	AACE, 2007 ACOG, 2001 ADA, 2006	Type 1 diabetes, Type 2 diabetes, and gestational diabetes	**Equipment and supplies for blood-glucose self-monitoring:** There is *clear and convincing evidence* that tight glycemic control using techniques to self-monitor blood glucose plays an important role in the management of Type 1, Type 2, and gestational diabetes mellitus (GDM), especially for persons whose glycemic levels are not well-controlled.[11] **Insulin therapy:** There is *clear and convincing evidence* that those with Type 1 diabetes should initiate intensive insulin therapy upon diagnosis. There is *clear and convincing evidence* to consider using insulin therapy for those with Type 2 diabetes if hemoglobin A_{1c} levels are greater than 8% and if symptomatic for hyperglycemia. Insulin therapy is also recommended for patients if they exhibit elevated fasting blood glucose levels. There is a *preponderance of evidence* that insulin therapy should be considered when medical nutrition therapy has not resulted in proper fasting glucose levels in pregnant females with GDM. **Prescription medications:** There is *clear and convincing evidence* that those diagnosed with Type 2 diabetes should be prescribed pharmacologic interventions, as part of a multi-component treatment regimen. The pharmacologic therapy should be persistently monitored and titrated until all glycemic goals are achieved. **Glucagon therapy:** There is expert *consensus* that glucagon should be prescribed for all diabetic patients at significant risk of severe hypoglycemia.

[11] There is *clear and convincing evidence* that persons with Type 1 diabetes who are being treated with insulin should glucose levels before administering a dose of insulin by injection or before changing the rate of insulin infusion delivered by an insulin pump. There is a *preponderance of evidence* to apply these same guidelines to those with Type 2 diabetes.

Topic	Citation(s)	Diagnosis	Conclusion
			Devices for administration of insulin: There is a *preponderance of evidence* that insulin pump therapy is an effective alternative to multiple insulin injections for diabetic patients who are unable to achieve glycemic control using a regimen of multiple daily injections. Insulin pump therapy is also recommended for those for whom multiple injections are contraindicated. **Self-management training and education:** There is *clear and convincing evidence* that all individuals with diabetes mellitus should be referred for comprehensive education in diabetes self-management skills and nutrition therapy. Education should be (1) provided by a qualified health care professional, (2) focus on all aspects of diabetes self-management relevant to each patient's treatment plan, (3) promote behavioral changes to support effective and consistent application of the prescribed diabetes treatment plan, and (4) be continued as an ongoing intervention to accommodate changes in the treatment plan and patient status. **Medical nutrition therapy:** There is *clear and convincing evidence* that medical nutrition therapy is an essential component of any diabetes mellitus management program, and that meal composition affects glycemic control and cardiovascular risk. There is *clear and convincing evidence* that modest weight loss reduces insulin resistance in overweight and obese insulin-resistant individuals; weight loss is recommended for all individuals who are overweight or obese and at risk for diabetes. There is *insufficient evidence* to recommend for or against moderate caloric restriction in obese females with GDM. **Podiatric devices used to prevent or treat foot-related complications:** Podiatric devices used to prevent or treat foot-related complications stemming from diabetes mellitus are discussed elsewhere in the section on special footwear.

Topic	Citation(s)	Diagnosis	Conclusion
Osteoporosis	ICSI, 2006 SIGN, 2003	Osteoporosis	**<u>Diagnosis</u>** There is *clear and convincing evidence* that bone mineral density (BMD) should normally be measured by dual-energy X-ray absorptiometry (DXA)[12] scanning performed on two sites, preferably anteroposterior spine and hip.[13] There is *a preponderance of evidence* that conventional radiographs should not be used for the diagnosis or exclusion of osteoporosis. There is a *preponderance of evidence* that when plain films are interpreted as "severe osteopaenia" it is appropriate to suggest referral for DXA. There is *clear and convincing evidence* that biochemical markers of bone turnover have no role in the diagnosis of osteoporosis or in the selection of patients for BMD measurement. Expert *consensus* recommends that there is no role for forearm or heel scanning in the diagnosis of osteoporosis in targeting therapy to reduce fracture risk. **<u>Treatment/Management</u>** **Exercise:** There is a *preponderance of evidence* that high intensity strength training and low-impact weight-bearing exercise be recommended as part of a management strategy for osteoporosis. **Calcium and Vitamin Intake:** There is *clear and convincing evidence* that postmenopausal females should

[12] DEXA is an effective diagnostic test for bone mineral loss or osteopenia. Osteoporosis is the most common type of osteopenia, but osteomalacia from vitamin D deficiency also causes bone mineral loss on DEXA testing.

[13] Regardless of medical history, risk of osteoporosis is elevated for individuals receiving exogenous glucocorticoid therapy and individuals accepted into transplantation programs. Persons taking exogenous glucocorticoids should receive preventive, diagnostic, and treatment services. Persons accepted into the transplantation programs should receive BMD on a yearly basis.

Topic	Citation(s)	Diagnosis	Conclusion
			take 1,000 mg of calcium per day. There is *clear and convincing evidence* to recommend oral calcium and vitamin D supplements to frail elderly females who are housebound to reduce hip fracture risk. **Hormone Replacement Therapy:** Expert *consensus* recommends that use of hormone replacement therapy (HRT) be considered as a treatment option for osteoporosis, but the risks and benefits should be discussed with each individual woman before starting treatment. **Pharmaceuticals:** There is *clear and convincing evidence* that pharmaceutical treatment reduces fracture risk at all sites for the following groups of postmenopausal females: (1) those who have had at least two vertebral fractures, (2) those who have had at least one vertebral fracture and osteoporosis confirmed by DXA scanning, and (3) those who have had low bone mineral density confirmed by DXA scanning. There is *clear and convincing evidence* to recommend that males with low bone mineral density and/or history of one or more vertebral fractures or one nonvertebral osteoporotic fracture be treated with pharmaceuticals to reduce fracture risk at all sites.

Topic	Citation(s)	Diagnosis	Conclusion
Transplantation services for persons with HIV	CHBRP, 2005b	Diseases requiring solid organ transplants	The available studies of organ transplantation in HIV-positive patients consist primarily of studies of kidney and liver transplantation, with only a few reports of heart transplantation, multiple organ transplantation, and autologous stem cell transplantation for lymphoma after high-dose chemotherapy. Most studies were performed in institutions that impose strict selection criteria on HIV-positive patients before transplantation.[14] Evidence from case series and case reports show that patients with HIV undergoing kidney transplantation have survival rates similar to survival rates of patients without HIV, and also have similar graft survival rates. Available sources of evidence show that, in persons who do not have hepatitis C, patient and graft survival rates after liver transplantation are similar regardless of HIV status.
Phenylketonuria —medical formula and medical foods	Fernandes et al., 2006; Nyhan et al., 2005	Phenylketonuria	A *preponderance of evidence* suggests that screening newborns for an elevated concentration of phenylalanine (Phe)[15] in the blood and performing diagnostic tests following positive screens is *effective* in identifying children who have phenylketonuria (PKU). A *preponderance of evidence* suggests that ingesting Phe-free medical formulas, low protein medical foods, and foods that are naturally low in Phe is *effective* in reducing the severity of mental and behavioral disorders associated with PKU. A *preponderance of evidence* suggests that early initiation of treatment improves outcomes and that periodic monitoring is necessary to assure that

[14] Only patients with evidence of a minimum level of immune function (CD4 T-cell5 counts greater than 100/ml) and undetectable HIV RNA6 levels were considered for transplantation. The major exceptions were patients with end-stage liver disease who could not tolerate drug therapy because of liver toxicity. Patients who were HIV-positive also were required to be free of opportunistic infections.

[15] Phenylalanine is an amino acid that persons with PKU cannot metabolize properly. Inability to metabolize phenylalanine causes toxic amounts of this amino acid and phenylketones to accumulate in the blood, which can lead to mental retardation, behavioral problems, and other disorders if untreated.

Topic	Citation(s)	Diagnosis	Conclusion
			the amount of Phe in the blood is maintained at a safe level. A *preponderance of evidence* suggests that some persons with PKU can tolerate more Phe in their diets as they grow older, but that some restriction of Phe intake is necessary throughout life.

Part C. Mental Illness and Substance Abuse

Topic	Citation(s)	Diagnosis	Conclusion
Parity in coverage for severe mental illness[16]	APA, 2000 NCCMH, 2006	Bipolar disorder	**Medication:** The *preponderance of evidence* indicates that medication is an effective treatment for bipolar disorder. [17] Much of the evidence regarding the efficacy of medications used to treat bipolar disorder comes from short-term studies (3 to 8 weeks) that may not indicate whether medications are effective over longer periods of time. **Psychotherapy:** There is a *preponderance of evidence* that combining medication and psychotherapy yields better outcomes for persons with bipolar disorder than medication alone.[18] **Electroconvulsive Therapy:** A *preponderance of evidence* indicates that electroconvulsive therapy (ECT) is as effective as medication in treating bipolar disorder. The evidence also suggests that combining ECT and medication is more effective than medication alone.

[16] Due to the limited time available to complete this report, the review of the evidence regarding the effectiveness of treatment for mental illness focuses on three of the most severe mental illnesses: bipolar disorder, major depressive disorder, and schizophrenia.
[17] Evidence of the relative efficacy of medications used to treat bipolar disorder (e.g., lithium, divalproex) was not examined.
[18] Although most research studies evaluate a single type of psychotherapy (e.g., cognitive behavioral therapy, interpersonal therapy), in practice most mental health professionals use a combination of treatment approaches. The relative efficacy of different types of psychotherapy used to treat bipolar disorder was not evaluated.

Topic	Citation(s)	Diagnosis	Conclusion
	APA, 2000 NCCMH, 2004	Major depressive disorder	**Medication:** There is *clear and convincing evidence* that antidepressant medications are effective treatments for major depressive disorder.[19] Much of the evidence regarding the efficacy of antidepressant medications comes from short-term studies (3 to 10 weeks) that may not indicate whether medications are effective over longer periods of time. **Psychotherapy:** There is *clear and convincing evidence* that most forms of psychotherapy are effective treatments for major depressive disorder.[20] **Electroconvulsive Therapy:** A *preponderance of evidence* indicates that ECT is an effective treatment for major depressive disorder and may be more effective than medication for some persons. **Light Therapy:** Evidence from a small number of studies suggests that light therapy is an effective treatment for persons with major depression that becomes more pronounced during winter.
	APA, 2000 NCCMH, 2003	Schizophrenia	**Medication:** A *preponderance of evidence* indicates that medication is an effective treatment for schizophrenia. Much of the evidence regarding the efficacy of medications used to treat schizophrenia comes from short-term studies (4 to 8 weeks) that may not indicate whether medications are effective over longer periods of time. **Psychosocial Interventions:** A *preponderance of evidence* indicates that providing psychosocial

[19] Evidence of the relative efficacy of antidepressant medications was not assessed.
[20] The relative efficacy of different types of psychotherapy for treating major depressive disorder was not examined.

Topic	Citation(s)	Diagnosis	Conclusion
			interventions in addition to medication improves outcomes for persons with schizophrenia. The following psychosocial interventions have been found to be effective adjuvant treatments for schizophrenia: assertive community treatment, cognitive behavioral therapy, crisis resolution teams, and family education and counseling.[21] **Electroconvulsive Therapy:** A *preponderance of evidence* indicates that antipsychotic medications are more effective than ECT for treatment of schizophrenia. A *preponderance of evidence* indicates that treating patients with both antipsychotic medications and ECT is more effective than treating them with antipsychotic medication alone.
Coverage for mental illness			Evidence regarding the effectiveness of treatment for mental illness is addressed elsewhere in the section on parity in coverage for severe mental illness.
Alcoholism treatment	APA, 2006 Mann et al., 2004 Srisurapanont et al., 2007	Alcoholism	**Pharmacological treatments:** There is *clear and convincing evidence* to recommend the use of benzodiazepines in the treatment of alcohol withdrawal. There is a *preponderance of evidence* that anticonvulsants and benzodiazepines have comparable efficacy in preventing seizures during alcohol withdrawal. Expert *consensus* recommends use of antipsychotic agents as an adjunct to

[21] Assertive community treatment involves the provision of intensive case management services in individuals' homes and neighborhoods to ensure compliance with treatment regimens and furnish assistance with activities of daily living and obtaining employment and/or education. Cognitive behavioral therapy is a type of psychotherapy that focuses on helping individuals identify problematic cognitive patterns and develop more effective strategies for coping with challenges. Crisis resolution teams are teams of mental health professionals who assist persons with schizophrenia who are experiencing crises. Family education and counseling seeks to provide the families and close friends of persons with schizophrenia with education about the disease and with training in stress reduction, communications, coping, and problem-solving skills.

Topic	Citation(s)	Diagnosis	Conclusion
			benzodiazepines to treat patients who manifest delirium, delusions, or hallucination. There is *clear and convincing evidence* to recommend Naltrexone (NTX) as a short-term treatment for alcohol dependence. There is *clear and convincing evidence* to recommend Acamprosate for the treatment of alcohol dependence as it enhances abstinence in recently detoxified, alcohol-dependent individuals who are concomitantly receiving psychosocial treatment. There is a *preponderance of evidence* to recommend Disulfiram as an effective adjunct to a comprehensive treatment program for reliable, motivated individuals whose drinking may be triggered by events that suddenly increase alcohol craving. Expert *consensus* does not recommend that thiamine be given routinely to all patients with moderate to severe alcohol use disorder to treat or prevent common neurological sequelae of chronic alcohol use. There is *insufficient evidence* to recommend the use of intravenous ethanol to treat alcohol withdrawal symptoms. **Psychosocial Treatments:** There is *clear and convincing evidence* that multiple forms of psychotherapy are effective treatments for alcohol use disorder. Effective psychotherapy treatments include cognitive behavioral therapy, motivational enhancement therapy, 12-step facilitation therapy, individual behavioral therapy, and marital and family therapy. There is a *preponderance of evidence* that greater participation in Alcoholics Anonymous (AA) is associated with greater rates of abstinence from alcohol for those individuals with an alcohol use disorder. Expert *consensus* suggests that group or individual psychodynamically

Topic	Citation(s)	Diagnosis	Conclusion
			oriented psychotherapies are effective for the treatment of individuals with an alcohol use disorder when combined with other psychosocial treatments or medications. **Treatment settings:** Expert *consensus* recommends that patients with alcohol withdrawal be detoxified in settings that provide for frequent clinical assessment and the provision of any necessary treatments. Expert *consensus* deems outpatient settings appropriate treatment settings for patients considered to be at low risk for a complicated withdrawal syndrome. In outpatient settings, medical detoxification is accomplished by using recommended medications. Intensive outpatient care involving frequent visits or conducted in a day hospital is preferable for the early phase of treatment because it facilitates frequent monitoring and access to necessary treatment. Expert *consensus* recommends that individuals be admitted to a residential or hospital setting if they have a history of withdrawal seizures or delirium tremens, have a documented history of very heavy alcohol use, are concurrently abusing other substances, have a severe comorbid general medical or psychiatric disorder, or repeatedly fail to cooperate with or benefit from outpatient detoxification.

Part D. Orthotics and Prosthetics

Topic	Citation(s)	Diagnosis	Conclusion
Orthotics and Prosthetics	CHBRP, 2006b	Multiple diagnoses	Use of prosthetic devices has been the standard of care for amputations and congenital limb deformities for so long that their benefits are widely accepted even though there are very few controlled studies of prosthetics versus no treatment. A *preponderance of evidence* from small studies suggests that newer technologies for prosthetic legs and feet result in an increase in speed, stride length, and stability during walking for young and middle-aged adults who are healthy and active. There is *insufficient evidence* to determine whether these new technologies benefit children or older adults who have a sedentary lifestyle and/or major comorbidities. There is *insufficient evidence* regarding the effects of new technologies used in upper limb prostheses.
	McLauchlan and Handoll, 2001	Achilles tendonitis	There is *insufficient evidence* to ascertain whether heel pads are an effective treatment for Achilles tendonitis.
	Felson et al., 2000	Deviation of the big toe and bunions	There is a *preponderance of evidence* that foot orthoses are not effective treatments for deviation of the big toe or bunions.
	Brouwer et al., 2005	Osteoarthritis	There is a *preponderance of evidence* that knee orthoses are effective treatments for osteoarthritis of the knee.
	D'Hondt et al., 2002	Patellofemoral pain syndrome	There is *insufficient evidence* to ascertain whether heel pads are an effective treatment for patellofemoral pain syndrome (i.e., soreness around the kneecap).
	Crawford and Thomson, 2003	Plantar heel pain	There is *insufficient evidence* to ascertain whether heel pads are an effective treatment for plantar heel pain.
	Clark et al., 2006; Egan et al., 2003	Rheumatoid arthritis	There is a *preponderance of evidence* that foot orthoses are effective treatments for rheumatoid arthritis of the foot.
	Handoll et al., 2001 Yeung and Yeung, 2001	Sprains and strains	There is a *preponderance of evidence* that ankle orthoses are effective for prevention of sprains and strains. There is *insufficient evidence* to determine whether foot orthoses are effective for prevention of sprains and strains.

Topic	Citation(s)	Diagnosis	Conclusion
	Rome et al., 2005	Stress fractures	There is *insufficient evidence* to determine whether foot orthoses are effective for prevention of stress fractures.
Prosthetic devices for persons who have had a laryngectomy	Evitts and Searl, 2006	Cancer of the larynx Severe injury to the larynx	**Tracheoesophageal speech with voice prosthesis[22] vs. normal speech:** Evidence from a single nonrandomized study suggests that the cognitive effort required for listeners to understand tracheoesophageal speech with voice prosthesis is similar to the cognitive effort required to understand normal speech.
	Arias et al., 2000; Globlek et al., 2004; Stajner-Katusic et al., 2004		**Tracheoesophageal speech with voice prosthesis vs. esophageal speech vs. electrolaryngeal speech:** Evidence from three small nonrandomized studies suggests that tracheoesophageal speech with voice prosthesis is more intelligible than esophageal speech and electrolaryngeal speech.
	Evitts and Searl, 2006		Evidence from a single nonrandomized study suggests that the cognitive effort required for listeners to understand tracheoesophageal speech with voice prosthesis is less than the cognitive effort required to understand esophageal speech and electrolaryngeal speech.
	Carr et al., 2000; Farrand and Duncan, 2007; Tsai et al, 2002		Evidence of the effect of tracheoesophageal speech with voice prosthesis relative to esophageal speech and electrolaryngeal speech on self-reported ability to communicate in daily life situations (e.g., talking on the telephone) is *ambiguous*.
	Carr et al., 2000; Farrand and Duncan, 2007		A *preponderance of evidence* from two nonrandomized studies suggests that quality of life does not differ among persons with laryngectomies who use tracheoesophageal speech with voice prosthesis, esophageal speech, or electrolaryngeal speech.

[22] Persons who have a laryngectomy lose the ability to speak normally. The three methods most frequently used to enable persons with largynectomies to speak are esophageal speech, electrolarygneal speech, and tracheosophageal speech with voice prosthesis. Esophageal speech involves the use of the esophagus to produce sound in place of the larynx. Tracheoesophageal speech is generated through use of a one-way, prosthetic valve that is placed in an incision between the esophagus and the trachea. This prosthesis allows air from the lungs to flow into the esophagus to produce sound. Electrolaryngeal speech is produced by a battery-operated machine that is held against the neck or placed in a small tube in the corner of the mouth. Speech therapy is needed to successfully use any of these three methods.

Topic	Citation(s)	Diagnosis	Conclusion
Special footwear for persons with foot disfigurement	Maciejewski et al., 2004; McIntosh, et al., 2003	Diabetes	The evidence of the effectiveness of therapeutic footwear in preventing diabetic foot ulcers is *ambiguous*. There is *insufficient evidence* to determine whether therapeutic footwear prevents amputation among persons with diabetes. Evidence from two small RCTs suggests that therapeutic shoes are *less effective* than total contact casting in facilitating healing of diabetic foot ulcers. There is *insufficient evidence* that combining therapeutic footwear with orthoses provides better protection from diabetic foot ulcers than therapeutic footwear alone.
	Farrow et al., 2005	Rheumatoid arthritis	A *preponderance of evidence* from small studies suggests that therapeutic shoes are effective in improving functioning and reducing pain and inflammation in persons with rheumatoid arthritis. There is *insufficient evidence* to determine whether combining therapeutic shoes and orthoses yields greater reductions in pain and inflammation due to rheumatoid arthritis than therapeutic shoes alone.
		Other diagnoses	No studies of the effectiveness of special footwear for persons with foot disfigurement due to causes other than diabetes or rheumatoid arthritis were found.

Part E. Pain Management

Topic	Citation(s)	Diagnosis	Conclusion
Acupuncture	CHBRP, 2007b	Multiple Diagnoses	**Acupuncture vs. No Treatment:** A *preponderance of evidence* suggests that needle acupuncture[23] is *more effective* than no treatment in reducing pain and improving the functioning of persons with some musculoskeletal conditions and chronic headache. **Acupuncture vs. Sham Acupuncture:** A *preponderance of evidence* suggests that needle acupuncture is *more effective* than sham acupuncture for treatment of some musculoskeletal conditions and postoperative nausea and vomiting. A *preponderance of evidence* suggests that needle acupuncture is *not more effective* than sham acupuncture for facilitating recovery from cocaine addiction and smoking cessation. **Acupuncture vs. Other Nonsurgical Treatments:** A *preponderance of evidence* suggests that needle acupuncture is *as effective as or more effective than other nonsurgical treatments* for osteoarthritis of the knee, temporomandibular joint (TMJ) disorders, pelvic pain associated with pregnancy, chronic headache, and postoperative nausea and vomiting. **Acupuncture in Conjunction with Other Nonsurgical Treatments:** A *preponderance of evidence* suggests that needle acupuncture is an *effective* adjuvant treatment for chronic low back pain, pelvic pain, stroke, and chemotherapy-induced vomiting. A *preponderance of evidence* suggests that needle acupuncture is *not an effective* adjuvant treatment for facilitating recovery from cocaine addiction and smoking cessation.

[23] Needle acupuncture refers to the use of acupuncture needles to stimulate acupressure points. Evidence regarding other services provided by acupuncturists, such as cupping and moxibustion, was not assessed.

Topic	Citation(s)	Diagnosis	Conclusion
Pain management medication for persons with terminal illnesses	AHRQ, 2001	Multiple diagnoses	Most of the research on pain management for persons with life-threatening illness has focused on cancer pain. Some of these studies include both persons whose cancers are terminal and persons who cancers are treatable. A *preponderance of evidence* suggests that nonsteroidal anti-inflammatory drugs (NSAIDs), opioids, antidepressants, anticonvulsants, and biophosponates[24] reduce pain caused by cancer or cancer treatment. A *preponderance of evidence* suggests that nonsteroidal anti-inflammatory drugs (NSAIDs) and "weak" opioids have similar effects on cancer-related pain. A *preponderance of evidence* suggests that administering "weak" opioids in conjunction with NSAIDs does not provide greater relief from cancer-related pain than NSAIDs alone. The evidence of the effects on pain relief of administering both opioids and psychostimulants relative to opioids alone is *ambiguous*.
General anesthesia for dental procedures	AAP and AAPD, 2006; AAPD, 2004; AAPD, 2006; ADA, 2005	Dental conditions	*The use of general anesthesia and other forms of sedation is usually based on consensus rather than scientific evidence.* Findings from studies of the use of general anesthesia for medical procedures suggest that general anesthesia is effective for young children and children who are extremely anxious or fearful about dental procedures. There is *consensus* that general anesthesia should be provided to children undergoing dental procedures only when they are unable or unwilling to undergo the procedure using a local anesthetic or nitrous oxide.

[24] Biophosponsates are typically used to treat pain caused by bone cancer or by metastatic tumors that have spread to bones from other organs.

Topic	Citation(s)	Diagnosis	Conclusion
			There is *consensus* that general anesthesia is also appropriate for persons with mental or physical disabilities that impede their ability to cooperate during dental procedures, persons for whom local anesthesia cannot be used due to allergy or acute infection, and persons who require extensive dental care or dental surgical procedures. Experts disagree as to whether general anesthesia should be provided to dental patients only in hospitals.

Part F. Pediatric Health Services

Topic	Citation(s)	Service	Conclusion
Comprehensive preventive care for children aged 16 years or younger consistent with the AAP's recommendations for preventive pediatric health care and the Recommended Childhood Immunization Schedule issued jointly by AAFP, AAP, and CDC ACIP	USPSTF, 1996; CDC growth charts for the United States; National Center for Health Statistics, 2000	Measurement: height, weight, blood pressure, head circumference	There is *consensus* for measurement of height, weight, and head circumference for newborns and infants aged up to 24 months. There is *consensus* for measurements of height, weight, and blood pressure for children aged 3 through 16 years.
	USPSTF, 2006; Recommendations for Preventive Pediatric Health Care, AAP, 2000; CHBRP 2007	Hearing screening	There is *insufficient evidence* to recommend for or against routine screening of newborns for hearing loss during the postpartum hospitalization. Studies have found that early diagnosis and treatment of hearing loss improves speech and language outcomes. However, these studies do not demonstrate that newborn hearing screening is effective, because they only assess children with hearing loss. They do not provide the information necessary to determine

Topic	Citation(s)	Service	Conclusion
			whether the benefits of screening for children with hearing loss exceed the harms associated with false positive results (e.g., anxiety, unnecessary diagnostic tests and treatments). There is *consensus* that sensory screening for hearing abnormalities should be provided to children aged 3 through 16 years if one suspects a hearing problem, except for the following intervals when standardized testing should be performed: from age 3 to 10, age 12 and age 15.
	USPSTF, 2004; Recommendations for Preventive Pediatric Health Care, AAP, 2000	Vision screening	There is a *preponderance of evidence* to screen for detection of visual impairment in children younger than 5 years. There is *consensus* that sensory screening for vision abnormalities should be provided to children aged 3 through 16 years if one suspects a vision problem, except for the following intervals when standard testing should be performed: from age 3 to 10, age 12 and age 15.
	Recommendations for Preventive Pediatric Health Care, AAP, 2000	Routine developmental/ behavioral assessments	There is *consensus* for routine developmental and behavioral assessments for newborns and children aged 0 through 16 years.
	Recommendations for Preventive Pediatric Health Care, AAP, 2000	Periodic physical examinations	There is *consensus* for routine physical examinations for children and adolescents through age 16.[25]
	USPSTF, 1996	Metabolic disorders: newborn screening	There is *a preponderance of evidence* that newborns should be screened for metabolic disorders shortly after birth (e.g., thyroid, hemoglobinopathies, PKU, galactosemia).

[25] There is evidence that providing periodic health examinations for adults aged 18 or older increases the likelihood that they will receive recommended preventive services (AHRQ, 2006).

Topic	Citation(s)	Service	Conclusion
	USPSTF, 2006	Screening for iron deficiency anemia	There is *insufficient evidence* to recommend for or against routine screening for iron deficiency anemia in asymptomatic children aged 6 months through 12 months. There is *consensus* for detecting the presence of iron deficiency by hematocrit or hemoglobin screening tests among high risk children aged 15 months through 5 years.
	Recommendations for Preventive Pediatric Health Care, AAP, 2000	Urinalysis	There is *consensus* for performing routine urinalysis for children aged 5 years and among sexually active adolescents and young adults aged 11 through 21 years.
	USPSTF, 2006	Screening for blood lead levels	Evidence regarding lead screening for children is discussed elsewhere.
	Recommendations for Preventive Pediatric Health Care, AAP, 2000	Tuberculin testing	For children aged 1 year through 16 years, there is *consensus* for tuberculin testing for individuals at high-risk for acquiring tuberculosis.
	Recommendations for Preventive Pediatric Health Care, AAP, 2000	Cholesterol screening	There is *consensus* for cholesterol screening for children aged 2 through 16 years who are at high risk for hypercholesterolemia.
	USPSTF, 2004-2007	Sexually transmitted disease screening	There is a *preponderance of evidence* that screening should be performed for sexually active adolescents aged 11 through 16 years who are at increased risk for contracting most sexually transmitted diseases. There is *insufficient evidence* for screening asymptomatic adolescents for herpes simplex virus (HSV). There is *consensus* that pelvic examinations should be performed for sexually active adolescent females. There is a preponderance of evidence that sexually active adolescent females should receive Pap smears. Guidelines for routine Pap smears are discussed in further detail elsewhere under recommendations for cervical cancer screening.

Topic	Citation(s)	Service	Conclusion
	USPSTF, 1996	Counseling parents and children regarding nutrition, injury prevention, and violence prevention	There is a *preponderance of evidence* that counseling with regard to nutrition and unintentional injury prevention is effective in improving dietary habits and in reducing injury rates, respectively, among children and adolescents. There is *insufficient evidence* to date to demonstrate that preventive counseling pertaining to violence reduces future intentional injuries or killings among youth.
	Recommendations for Preventive Pediatric Health Care, AAP, 2000	Counseling parents regarding infant sleeping position	There is *consensus* that counseling about sleep position be provided to parents of infants through age 6 months.
	Recommendations for Preventive Pediatric Health Care, AAP, 2000	Dental examinations	There is *consensus* that periodic preventive dental examinations be performed for children aged 12 months to 3 years.
	USPSTF, 1996	Diphtheria and tetanus toxoids and acellular pertussis (DTaP) vaccine	A *preponderance of evidence* indicates that combined vaccines for diphtheria, tetanus, and pertussis are effective in preventing these diseases. Combined vaccines that contain acellular forms of the pertussis vaccine provide the same level of protection as vaccines that contain whole cell pertussis vaccine and are associated with fewer local and systemic side effects.
	USPSTF, 1996	Haemophilus influenza type B (Hib) conjugate vaccine	A *preponderance of evidence* indicates that the Hib vaccine is safe and effective in preventing haemophilus influenza type B.
	USPSTF, 1996	Hepatitis A vaccine	A *preponderance of* evidence indicates that the hepatitis A vaccine is safe and effective in preventing hepatitis A infection. The evidence suggests that two doses are necessary to obtain optimal protection.

Topic	Citation(s)	Service	Conclusion
	USPSTF, 1996	Hepatitis B vaccine	A *preponderance of evidence* indicates that the hepatitis B vaccine is safe and effective in preventing infection with the hepatitis B virus and chronic infection.[26] The evidence also suggests that two doses of the vaccine are needed to provide adequate protection over the long-term. In addition, the evidence suggests that combining the vaccine with hepatitis B immunoglobulin may provide better protection for infants whose mothers have chronic hepatitis B infection.
	CHBRP, 2007a	Human papillomavirus (HPV) vaccine	A *preponderance of evidence* suggests that the human papillomavirus (HPV) vaccine is effective in preventing the four strains of HPV that account for most cervical cancers and anogenital warts for at least five years post-vaccination. The vaccine has only been tested in females aged 16 to 26 years who had no prior HPV infection, but there is *consensus* that the vaccine should be given to all females aged 11 to 26 years regardless of prior exposure to HPV. There is no evidence that the vaccine is associated with severe adverse events.
	CDC ACIP, 2000 USPSTF, 1996	Inactivated poliovirus vaccine	A *preponderance of evidence* indicates that the oral poliovirus vaccine prevents polio, but there is a very small risk that children who are vaccinated will contract the disease. The evidence also suggests that inactivated poliovirus vaccine is as effective as the oral poliovirus vaccine and is not associated with adverse effects.
	USPSTF, 1996	Influenza vaccine	A *preponderance of* evidence suggests that influenza vaccines are effective in preventing influenza in persons of all ages, although most of the research has been conducted on elderly adults.
	USPSTF, 1996	Measles, mumps, and rubella (MMR) vaccine	A *preponderance of evidence* indicates that the MMR vaccine is effective in preventing measles, mumps, and rubella. The evidence also indicates that a two-dose regimen may be more effective than a one-dose regimen, because some persons do not obtain immunity from the first dose, especially if the first dose is given during infancy. The second dose should be administered at age 4 to 6 years.

[26] Some persons infected with hepatitis B do not recover from their infections. Persons with chronic hepatitis B infection are at increased risk of contracting cirrhosis of the liver, liver cancer, and other liver diseases.

Topic	Citation(s)	Service	Conclusion
	CDC, 2005c	Meningococcal polysaccharide (MPSV4) vaccine	A *preponderance of evidence* indicates that the MPSV4 vaccine is safe and effective in preventing meningococcal disease. The evidence also suggests that inoculating children with both MPSV4 and meningococcal conjugant vaccine (MCV4) is more effective than administering two doses of MPSV4.
	CDC, 2005c	Meningococcal conjugant (MCV4) vaccine	A *preponderance of evidence* indicates that the MCV4 vaccine is safe and is as effective as the MPSV4 vaccine in preventing meningococcal disease.
	USPSTF, 1996	Pneumococcal polysaccharide vaccine	A *preponderance of evidence* indicates that pneumococcal polysaccharide vaccine is effective in preventing pneumococcal infection among persons whose immune systems are not compromised.
	CDC, 2006	Rotavirus vaccine	A *preponderance of evidence* indicates that the rotavirus vaccine prevents rotavirus gastroenteritis and that rates of serious adverse events are low and no worse than in control groups not receiving the vaccine.
	USPSTF, 1996	Tetanus and diphtheria toxoids and acellular pertussis (TDaP) vaccine	A *preponderance of evidence* indicates that combined tetanus, diphtheria, and pertussis vaccines (TDaP) are effective in preventing these diseases. Vaccination with the TDaP vaccine is recommended for older children who did not receive the DTaP vaccine between ages 0 and 6 years.
	USPSTF, 1996	Varicella vaccine	A *preponderance of evidence* indicates that the varicella vaccine is safe and effective in preventing chickenpox. The evidence also suggests that one dose of the vaccine is sufficient for children under age 13, but that two doses are needed for adolescents to receive optimal protection.
Comprehensive preventive care for children aged 16 years or younger consistent with the AAP's recommendations for preventive pediatric health care and the Recommended Childhood	Same as services recommended for children aged 0 to 16 years	Same as services recommended for children aged 0 to 16 years	There is *consensus* that all recommendations for preventive care that apply to those aged 3 to 16 years should also guide care for adolescents aged 17 and 18 years. Sensory screening for vision and hearing abnormalities for adolescents aged 17 years is recommended on a subjective basis, by history. Sensory screening for vision and hearing abnormalities for adolescents aged 18 years is recommended on an objective basis, by a standard testing method.

Topic	Citation(s)	Service	Conclusion
Immunization Schedule issued jointly by AAFP, AAP, and CDC ACIP			
Asthma management	Ahrens et al., 1995; CHBRP, 2004; CHBRP, 2006a; Dolovich et al., 2005; Feddah et al., 2001; NHLBI, 2007	Asthma	**Peak Flow Meters:** There is *clear and convincing evidence* that self-monitoring is an important component of self-management of asthma. A *preponderance of evidence* suggests that peak flow monitoring is *as effective as* symptom monitoring in identifying substances that trigger asthma exacerbations, determining whether medication needs to be adjusted,[27] and evaluating the impact of changes in medication. A *preponderance of evidence* suggests that daily peak flow monitoring is especially useful for persons who have moderate or severe persistent asthma or a history of severe asthma exacerbations. **Spacers:** A *preponderance of evidence* suggests that use of spacers in conjunction with conventional metered dose inhalers (MDIs) reduces the amount of medication a person swallows and, thus, reduces the risk of local adverse effects, such as oral thrush.[28] There is *insufficient evidence* to determine whether spacers reduce local adverse effects when used with new hydrofluoroalkane-propelled MDIs. [29] Evidence regarding the impact of spacers on the delivery of asthma medications to the lungs is *ambiguous*. Expert consensus suggests that spacers

[27] For example, a decrease in peak expiratory flow or symptoms of cough, wheezing, or chest tightness often indicate that a person should take a short-acting bronchodilator to open the airways in the lungs.
[28] Thrush is an oral yeast infection.
[29] Historically, MDIs have used chlorofluorocarbons (CFCs) to propel medication. CFCs are a major cause of ozone depletion. The U.S. Food and Drug Administration (FDA) has now mandated that CFC-based MDIs be removed from the market by 2009. They are being replaced by hydrofluoroalkane-propelled MDIs (HFA MDIs).

Topic	Citation(s)	Service	Conclusion
			are most helpful to persons who are having a severe asthma exacerbation or who cannot us MDIs properly (e.g., young children). Findings from laboratory studies suggest that effectiveness varies across asthma medications and across spacers with different features (e.g., integrated with MDI device, contains valved holding chamber, shape of chamber, rigid or flexible chamber). **Nebulizers:** The *preponderance of evidence* suggests that nebulizers and MDIs are equally effective in improving health outcomes for children with asthma. Nebulizers are recommended only for persons who cannot use a MDI with a spacer or a MDI with both a spacer and face mask, such as young children. **Asthma Education:** There is *clear and convincing evidence* that education in asthma self-management helps children and their parents learn skills necessary for controlling asthma and improving their health.
Screening children for blood lead levels	USPSTF, 2006	Lead poisoning	There is a *preponderance of evidence* that blood lead testing accurately detects elevated blood lead levels. There is *insufficient evidence* that medical treatment or lead abatement results in sustained decreases in blood lead levels or improved health outcomes in asymptomatic children. There is *insufficient evidence* to recommend for or against routine screening for elevated blood lead levels in asymptomatic children aged 1 through 5 years who are at *increased risk*.

Topic	Citation(s)	Service	Conclusion
			There is a *preponderance of evidence* to recommend *against* routine screening for elevated blood lead levels in asymptomatic children aged 1 through 5 years who are at *average risk* due to the significant potential harms of treatment.[30]

Part G. Reproductive Health Services

Topic	Citation(s)	Diagnosis	Conclusion
Contraceptive devices requiring a prescription	WHO, 2004	Pregnancy	**Prescription Contraceptives[31] vs. No Method of Contraception:** There is *clear and convincing evidence* that sexually active females who use prescription contraceptives are much less likely to become pregnant than sexually active females who do not use any form of contraception. **Prescription Contraceptives vs. Nonprescription Contraceptives[32]:** There is a *preponderance of evidence* that prescription contraceptives are more effective than nonprescription contraceptives for preventing pregnancy. However, prescription contraceptives *do not* protect against the human immunodeficiency virus (HIV). Condoms are the only form of contraception that prevents transmission of HIV.

[30] There is good evidence that chelation treatment in asymptomatic children does not improve neurodevelopmental outcomes and is associated with a slight diminution in cognitive performance. Chelation therapy may result in transient renal, hepatic, and other toxicity, mild gastrointestinal symptoms, sensitivity reactions, and rare life-threatening reactions. Residential lead-based paint and dust hazard control treatments may lead to acutely increased blood lead levels from improper removal techniques.

[31] Prescription contraceptives can be divided into three major categories. Barrier methods are devices inserted into the vagina that are used in conjunction with a spermicide and removed between episodes of intercourse. They include the cervical cap, the cervical shield, and the diaphragm. Intrauterine devices are small devices composed of copper wire wrapped around a plastic frame that are implanted in the uterus. Hormone-based contraceptives prevent ovulation and change the lining of the uterus and cervical mucus to prevent pregnancy. Multiple methods have been developed to deliver hormone-based contraceptives, including pills, injections, implants, skin patches, and vaginal rings.

[32] Non-prescription methods of contraception include condoms, spermicides, periodic abstinence, and withdrawal.

Topic	Citation(s)	Diagnosis	Conclusion
			Barrier Methods of Contraception vs. Intrauterine Devices (IUDs) vs. Hormone-based Contraceptives: There is *clear and convincing evidence* that hormone-based contraceptives and IUDs are more effective than barrier methods for preventing pregnancy. When used exactly as directed, IUDs and all forms of hormone-based contraceptives are equally effective for preventing pregnancy. However, effectiveness often differs in practice. Among typical users, IUDs and hormone-based implants are most effective, because females do not need to take further action once they are implanted. Females who use hormone-based injections, patches, vaginal rings, or pills have to take action every several months (injections), every month (patches and vaginal rings), or every day (oral contraceptives) to obtain additional doses of the contraceptive. The *preponderance of evidence* suggests that hormone-based contraceptives may alleviate endometriosis and reduce the risk of endometrial cancer, ovarian cancer, and pelvic inflammatory disease. Although most females can use all types of prescription contraceptives safely, there is *clear and convincing evidence* that females with certain health conditions should not use IUDs and/or hormone-based contraceptives.[33]
	French et al., 2004		**Hormonally impregnated IUDs vs. Copper IUDs:** There is clear and convincing evidence that hormonally impregnated IUDs are as effective as copper IUDs >250mm2 for preventing pregnancy, but are more effective than copper IUDs <=250mm2.
	Gallo et al., 2003		**Contraceptive Skin Patches vs. Oral Contraceptives:** There is clear and convincing evidence that contraceptive skin patches are as effective as oral contraceptives for preventing pregnancy.

[33] IUDs should not be used by women who have a distorted uterine cavity, malignant gestational trophoblastic disease, or active cases of pelvic tuberculosis, puerperal sepsis, chlamydia, gonorrhea, or purulent cervicitis. Hormone-based contraceptives should not be used by females with the following conditions: smoke more than 15 cigarettes per day, have had major surgery with prolonged immobilization, have had diabetes for over 20 years, have a history of or a current case of deep venous thrombosis, pulmonary embolism, ischaemic heart disease, or stroke, or currently have multiple major risk factors for cardiovascular disease, complicated valvular heart disease, known thrombogenic mutations, untreated or poorly controlled hypertension, vascular disease, migraine with aura, breast cancer, active viral hepatitis, cirrhosis of the liver, liver tumors, or diabetic nephropathy, neuropathy, or retinopathy.

Topic	Citation(s)	Diagnosis	Conclusion
	Gallo et al., 2005		**Injectable Contraceptives vs. Copper IUDs:** Evidence from one RCT suggests that injectable hormone-based contraceptives are as effective as copper IUDs for preventing pregnancy.

Topic	Citation(s)	Diagnosis	Conclusion
Infertility treatments	Attia et al., 2007 Luttjeboer et al., 2007 NCCWCH, 2004	Infertility	**<u>Diagnosis and investigation of fertility problems</u>** **Male Infertility:** There is *a preponderance of evidence* that if the results of a semen analysis test are abnormal, a repeat confirmatory test should be offered. **Female Infertility:** There is a *preponderance of evidence* that females with regular menstrual cycles and more than 1 year's infertility should be offered a blood test to measure serum progesterone to confirm ovulation. There is a *preponderance of evidence* that females should be offered hysterosalpingography (HSG) or hysterosalpingo-contrast-ultrasonography to screen for tubal occlusion if they are not known to have comorbidities, such as pelvic inflammatory disease, previous ectopic pregnancy, or endometriosis. There is a *preponderance of evidence* that females who are thought to have comorbidities be offered laparoscopy and dye so that tubal and other pelvic pathology can be assessed. There is a *preponderance of evidence* that females undergoing uterine instrumentation be offered screening for *Chlamydia trachomatis.* Those testing positive should be referred for appropriate treatment and contact tracing. Expert *consensus* recommends that females with prolonged irregular menstrual cycles should be offered a blood test to measure serum progesterone and serum gonadotrophins. There is *insufficient evidence* to recommend assessing ovarian reserve using inhibin B.

Topic	Citation(s)	Diagnosis	Conclusion
			There is *clear and convincing evidence* to not recommend routine use of postcoital testing of cervical mucus in the investigation of fertility problems because it does not accurately predict pregnancy rates. There is a *preponderance of evidence* to not recommend use of basal body temperature to confirm ovulation as it does not reliably predict ovulation. There is a *preponderance of evidence* that most females who are concerned about their fertility should not be offered a blood test to measure prolactin.[34] There is a *preponderance of evidence* that routine measurement of thyroid function should not be offered because females with potential infertility problems are no more likely than the general population to have thyroid disease. There is a *preponderance of evidence* to recommend that females not be offered hysteroscopy on its own as part of the initial investigation unless clinically indicated, because the effectiveness of surgical treatment of uterine abnormalities on improving pregnancy rates has not been established. There is *insufficient evidence* to determine whether testing for and treatment of luteal phase defect is effective as it does not improve pregnancy rates.

[34] This test should only be offered to women who have an ovulatory disorder, galactorrhoea or a pituitary tumor.

Topic	Citation(s)	Diagnosis	Conclusion
			<u>Medical Management</u> **Male Infertility:** There is a *preponderance of evidence* that males with hypogonadotrophic hypogonadism be offered gonadotrophin drugs because these are effective in improving fertility among males who have this condition. There is *clear and convincing evidence* that males with idiopathic semen abnormalities should not be offered anti-estrogens, gonadotrophins, androgens, bromocriptine or kinin-enhancing drugs because they have not been shown to be effective. There is *clear and convincing evidence* that males with leukocytes in their semen should not be offered antibiotic treatment unless there is an identified infection because there is no evidence that this improves pregnancy rates. **Female Infertility:** There is a *preponderance of evidence* that females with ovulation disorders such as hypothalamic pituitary failure should be offered ovulation induction therapy and pharmaceutical treatment. There is *clear and convincing evidence* that females with ovulation disorders stemming from hypothalamic pituitary dysfunction, such as polycystic ovary syndrome, be offered as the first line of treatment clomifene citrate as it is likely to induce ovulation. There is *clear and convincing evidence* that females be informed that clomifene citrate treatment increases the chance of pregnancy, but that this needs to be balanced by the possible risks of treatment, especially multiple pregnancy.
			Expert *consensus* recommends that females undergoing treatment with clomifene citrate be offered ultrasound monitoring during at least the first cycle of treatment to ensure that they receive a dose that minimizes the risk of multiple pregnancy.

Topic	Citation(s)	Diagnosis	Conclusion
			There is *clear and convincing evidence* that females with ovulation disorders such as polycystic ovary syndrome who do not ovulate with clomofine citrate be offered treatment with gonadotrophins. There is *clear and convincing evidence* that females with polycystic ovary syndrome who are being treated with gonadotrophins should not be offered treatment with gonadotrophin-releasing hormone agonist in tandem because it does not improve pregnancy rates, and it is associated with an increased risk of ovarian hyperstimulation. There is a *preponderance of evidence* that females who are offered ovulation induction with gonadotrophins should be informed about the risk of multiple pregnancy and ovarian hyperstimulation before starting treatment. There is a *preponderance of evidence* that females who are offered ovulation induction should be informed that the association between ovulation induction therapy and ovarian cancer remains uncertain. Practitioners should confine the use of ovulation induction agents to the lowest effective dose and duration of use. There is *clear and convincing evidence* that tubal flushing with oil-soluble contrast media increases the chance of pregnancy. There is *clear and convincing evidence* that medical treatment of minimal and mild endometriosis does not enhance fertility in subfertile females and should not be offered.
			<u>Surgical Management</u> **Male Infertility:** There is a *preponderance of evidence* that males who experience an inadequate measurable level of sperm in their semen be offered surgical correction of epididymal blockage because it is likely to improve fertility. There is *clear and convincing evidence* that males should not be offered surgery for varicoceles (abnormal enlargement of the veins in the scrotum

Topic	Citation(s)	Diagnosis	Conclusion
			draining the testicles) as a form of fertility treatment because it does not improve pregnancy rates. **Female Infertility:** There is *clear and convincing evidence* to recommend that females with minimal or mild endometriosis who undergo laparoscopy be offered surgical treatment for endometriosis because this improves the chance of pregnancy. There is a *preponderance of evidence* that females with moderate or severe endometriosis be offered surgical treatment because it improves the chance of pregnancy. There is *clear and convincing evidence* to recommend that females with ovarian endometriomas be offered laparoscopic cystectomy because this improves the chance of pregnancy. Expert *consensus* recommends that for females with mild tubal disease surgery may be more effective than no treatment. There is *clear and convincing evidence* that postoperative medical treatment does not improve pregnancy rates in females with moderate to severe endometriosis
			Intrauterine Insemination: There is *clear and convincing evidence* to recommend that couples with mild male factor fertility problems, unexplained fertility problems, or in which a female partner has minimal to mild endometriosis be offered up to six cycles of intrauterine insemination, as this increases the chance of pregnancy. There is *clear and convincing evidence* that, where intrauterine insemination is used to manage male factor fertility problems, ovarian stimulation should not be offered because it is no more clinically effective than unstimulated intrauterine insemination and it carries a risk of multiple pregnancy. There is *clear and convincing evidence* that, where intrauterine insemination is used to manage unexplained fertility problems, ovarian stimulation should not

Topic	Citation(s)	Diagnosis	Conclusion
			be offered even though it is associated with higher pregnancy rates than unstimulated intrauterine insemination, because it carries a risk of multiple pregnancy.
Prenatal Diagnosis of Genetic Disorders	ACOG Committee on Practice Bulletins, 2007 Alfirevic et al., 2003	Genetic abnormalities of fetus	There is *a preponderance of evidence* that available prenatal diagnostic procedures to identify genetic disorders of the fetus (e.g., amniocentesis, chorionic villus sampling) accurately identify all fetuses with these disorders. Current guidelines recommend that individuals be given the option to undergo invasive diagnostic procedures regardless of age.[35] Prenatal diagnostic procedures are invasive and pose a small risk of a procedure-related loss of a healthy fetus. Among widely used prenatal diagnostic procedures, there is *a preponderance of evidence* that second trimester amniocentesis is safer than chorionic villus sampling and early (first trimester) amniocentesis.
Expanded alpha-fetoprotein screening	ACOG Committee on Practice Bulletins, 2007	Down syndrome	There is a *preponderance of evidence* that screening by expanded alpha-fetoprotein tests detects likelihood of fetal Down syndrome at a rate of 70-80%. Screening for genetic disorders of the fetus provides an individual risk assessment but is not diagnostic and will not detect all abnormalities. It is recommended that *all* females be offered expanded alpha-fetoprotein screening before 20 weeks of gestation, regardless of maternal age. The benefits of expanded alpha-fetoprotein screening is that females who undergo diagnostic procedures are more likely to be carrying a fetus with genetic abnormalities and will have a lower risk of a procedure-related loss of

[35] In the past, the consensus among experts was to recommend prenatal diagnostic testing for genetic disorders only for women age 35 or older because they are the group at greatest risk for delivering a child with one of these disorders.
[36] Procedures used to diagnose genetic abnormalities can cause miscarriage or infection or injury to the fetus in a very small percentage of women who undergo them.

Topic	Citation(s)	Diagnosis	Conclusion
			a healthy fetus.[36] The potential harms of screening are that not all fetuses with genetic defects will be detected. Screening tests may also falsely indicate that a fetus has genetic abnormalities, which can lead to unnecessary anxiety and diagnostic testing.

Part H. Surgical Procedures

Topic	Citation	Diagnosis	Conclusion
Jawbone or associated bone joints	Reston and Turkelson, 2003	Temporo-mandibular joint disorder	A *preponderance of evidence* suggests that surgical treatments for temporomandibular joint disorders (TMJ) reduce pain among persons who do not respond to nonsurgical treatments. The three major surgical procedures for TMJ disorders (arthocentesis, arthroscopy, and disc repair/repositioning) appear equally effective in reducing pain.
Reconstructive surgery	Fung et al., 2001; Holly et al., 2003; Janz et al., 2005; Nano et al., 2005; Nissen et al., 2001; Pusic et al., 1999; Rowland et al., 2000; Rubino et al., 2006; Yurek et al., 2000	Breast cancer	**Body Image:** There is *ambiguous evidence* as to whether females who undergo mastectomy with breast reconstruction have better body image than in females who undergo mastectomy alone. There is a *preponderance of evidence* that body image is significantly better for those females who undergo breast-conserving therapy than in females who undergo mastectomy alone. **Quality of Life:** There is a *preponderance of evidence* that females who undergo breast-conserving therapy or mastectomy with breast reconstruction do not have a better quality of life than that experienced by females who undergo mastectomy alone.[37] **Depression/Mood Disturbance:** There is *insufficient evidence* to recommend mastectomy with breast

[37] Results of studies indicate that other factors such as age, exposure to adjuvant therapy, and educational level influence quality of life for women who undergo breast cancer treatments.

Topic	Citation	Diagnosis	Conclusion
			reconstruction or breast-conserving therapy as procedures to reduce depression or mood disturbance post-surgery relative to that experienced by females who undergo mastectomy alone. **Sexual Responsiveness:** There is *ambiguous evidence* to recommend mastectomy with breast reconstruction or breast-conserving therapy as procedures to assure better sexual responsiveness than that experienced by females who undergo mastectomy alone.
	Roye et al., 2001 Vitale et al., 2005	Clubfoot	There is expert *consensus* that surgery should be performed to correct clubfoot only if nonsurgical treatment involving manipulation, casting, and bracing is not effective. Only two small nonrandomized studies of overlapping groups of persons with clubfoot could be located. Persons who have had surgery to correct clubfoot are similar to persons with normal feet with regard to physical, psychological, and social functioning, but have lower self-reported health status. Most persons who have had surgery for clubfoot report that they have no or few limitations with regard to walking and running and rarely experience pain when exercising.
	Endriga and Kapp-Simon, 1999	Craniofacial abnormalities	The methodological quality of studies of persons who have had surgery for craniofacial abnormalities is low.[38] In addition, the impact of surgery cannot be easily assessed in children with craniofacial abnormalities, because treatment involves multiple surgical procedures that can extend throughout childhood and adolescence. Most studies have assessed persons with cleft lip and/or cleft palate because these disorders are more common than other craniofacial abnormalities.

[38] Many studies do not include comparison groups and those that do often use convenience samples of persons seeking preventive care or treatment for minor health problems.

Topic	Citation	Diagnosis	Conclusion
	Marcusson et al., 2001;Marcusson et al., 2002 Sarwer et al., 1999		Two small, nonrandomized studies found that despite corrective surgery, young adults with craniofacial abnormalities had poorer body image with regard to facial features and lower quality of life than young adults who did not have craniofacial disfigurement. One small, nonrandomized study reported that young adults who had undergone surgery for cleft lip and/or cleft palate were as well-adjusted psychologically as young adults who did not have craniofacial disfigurement, but perceived their health problems as interfering with family and social contacts.

Part I. Other Services

Topic	Citation	Diagnosis	Conclusion
Hospice care	Harding et al., 2005 Higginson et al., 2003 NICE, 2004	Multiple diagnoses	Hospice care encompasses of care and services provided to persons in the late stages of terminal illnesses to relieve pain and suffering and maximize quality of life prior to death and services provided to families to help them cope with a loved one's illness and their own bereavement. Studies of hospice care vary widely with regard to research design, study population, characteristics of the hospice intervention,[39] and outcomes assessed. This high degree of variability makes it difficult to generalize findings across studies. Most studies with strong research designs were published in the 1980s. Medications and standards of care for pain control may have changed since these studies were conducted. In addition, most studies evaluated the impact of hospice care on persons with terminal cancers. Their findings may not generalize to persons with other diseases and conditions who use hospice care. The *preponderance of evidence* suggests that hospice care reduces some symptoms associated with terminal illness, such as anxiety, diarrhea, and

[39] Some studies have assessed the delivery of hospice care in patients' homes. Others have examined inpatient hospice units in hospitals. Others have evaluated interventions that combined home-based and inpatient hospice services.

Topic	Citation	Diagnosis	Conclusion
			nausea. The evidence of the effects of hospice care on the duration, frequency, and severity of pain is *ambiguous*. The evidence of the effects of hospice care on hospital use and quality of life is *ambiguous*. The *preponderance of evidence* indicates that caregivers of persons with terminal illnesses were more satisfied with hospice care than usual care.
Home health care		Multiple diagnoses	Studies of home care vary widely with regard to study populations, characteristics of home care interventions, comparison groups,[40] and outcomes assessed. This high degree of variability makes it difficult to generalize findings across studies. In addition, many studies that assess the effects of home care versus usual care were published in the 1980s. The case mix and severity of illness or disability among persons using home care and the technologies used to treat them may have changed during the ensuing decades. Furthermore, most studies evaluated the impact of home care on elderly persons and many were conducted outside the United States. Their findings may not generalize to non-elderly Californians enrolled in commercial health plans.

[40] Some studies compare persons receiving home care to persons who receive "usual care," an undefined set of services typically available to persons in the communities in which the studies are undertaken. Other studies compare persons who receive rehabilitative services (e.g., physical therapy) in their homes to persons who receive similar services in inpatient settings.

Topic	Citation	Diagnosis	Conclusion
	Hedrick et al., 1989; Hughes et al., 1997 Parker et al., 2002	Multiple diagnoses	**<u>Home Care vs. Usual Care</u>** **Adults**: There is clear and convincing evidence that home care is associated with statistically significant reductions in days of hospitalization and nursing home use among adults and with a nonsignificant decrease in mortality relative to usual care. **Children:** A single RCT reported that home care for children is associated with greater parent satisfaction than usual care but that medical and psychological outcomes are similar.
	Parker et al., 2002	Asthma or diabetes	**<u>Home Care vs. Usual Care</u>** **Children:** The preponderance of evidence suggests that home care reduces length of hospital stay for children with asthma or diabetes.
	Parker et al., 2002	Very low birth weight	**<u>Home Care vs. Usual Care</u>** **Children:** The evidence regarding the impact of home care on length of hospital stay and hospital readmission for infants with very low birth weight is *ambiguous*. There is *insufficient evidence* to ascertain the effects of home care on emergency department use and clinical and developmental outcomes for infants with very low birth weight.

Topic	Citation	Diagnosis	Conclusion
	Cunliffe et al., 2004 Shepperd and Iliffe, 2005	Multiple diagnosis	**<u>Home-based Rehabilitation vs. Inpatient Rehabilitation</u>** There is *clear and convincing evidence* that home-based rehabilitation is associated with fewer days of hospitalization than inpatient rehabilitation. There is *clear and convincing evidence* that home-based rehabilitation and inpatient rehabilitation have similar effects on mortality, physical functioning, psychological functioning, quality of life, hospital readmission, and caregiver burden. The evidence regarding the impact of home-based rehabilitation on patient and caregiver satisfaction is *ambiguous*.
	Crotty et al., 2002; Giusti et al., 2006; Kuisma, 2002	Hip fracture	**<u>Home-based Rehabilitation vs. Inpatient Rehabilitation</u>** The *preponderance of evidence* suggests that persons with hip fracture who receive home-based rehabilitation have better physical functioning than persons who receive inpatient rehabilitation. There is *insufficient evidence* to determine whether the effects of home-based rehabilitation and inpatient rehabilitation for hip fracture differ with regard to falls, hospital readmission, hospital length of stay, or caregiver burden.

Topic	Citation	Diagnosis	Conclusion
	Early Supported Discharge Trialists 2005; Langhorne et al., 2007	Stroke	**<u>Home-based Rehabilitation vs. Inpatient Rehabilitation</u>** The *preponderance of evidence* indicates that, relative to inpatient rehabilitation for stroke, home-based rehabilitation is associated with greater probability of living in one's own home, better physical functioning, greater ability to engage in extended activities of daily living,[41] shorter length of hospital stay, and greater patient satisfaction. There is *clear and convincing evidence* that home-based rehabilitation and inpatient rehabilitation for stroke have similar effects on mortality, patient self-reported health status, hospital readmissions, caregiver satisfaction, and caregiver health status.

Legend for Sources of Evidence:
AACE = American Association of Clinical Endocrinologists**,** AAP = American Academy of Pediatrics, AAPD = American Academy of Pediatric Dentistry, ACOG = American College of Obstetricians and Gynecologists, ADA = American Dental Association, ADA = American Diabetes Association, AHRQ = Agency for Healthcare Research and Quality, APA = American Psychiatric Association, CDC ACIP = Centers for Disease Control and Prevention Advisory Committee on Immunization Practices, CHBRP = California Health Benefits Review Program, ICSI = Institute for Clinical Systems Improvement, NCCMH = National Collaborating Centre for Mental Health, NCCN = National Comprehensive Cancer Network, Inc., NCCWCH = British National Collaborating Centre for Women's and Children's Health, NHLBI = National Heart, Lung, and Blood Institute, NICE: National Institute for Clinical Excellence, NIH = National Institutes of Health, SIGN = Scottish Intercollegiate Guidelines Network, USPSTF = US Preventive Services Task Force, WHO = World Health Organization.

[41] Extended activities of daily living (also known as instrumental activities of daily living) are activities beyond basic physical functioning that enable persons to live independently in their own homes. Examples include cooking, doing housework, talking on the telephone, engaging in social activities, and driving or taking public transportation.

APPENDIX D: COST IMPACT ANALYSIS: DATA SOURCES, CAVEATS, AND ASSUMPTIONS

This appendix describes data sources, general and mandate-specific caveats and assumptions used in conducting the cost impact analysis. For additional information on the cost model and underlying methodology, please refer to the CHBRP Web site, www.chbrp.org/costimpact.html.

The cost analysis in this report was prepared by the Cost Team, which consists of CHBRP task force members and staff, specifically from the University of California, Los Angeles, and Milliman Inc. (Milliman). Milliman is an actuarial firm and provides data and analyses per the provisions of CHBRP authorizing legislation.

Data Sources

In preparing cost estimates, the Cost Team relies on a variety of data sources as described below.

Private health insurance

1. The latest (2005) California Health Interview Survey (CHIS), which is utilized to estimate insurance coverage for California's population and distribution by payer (i.e., employment-based, privately purchased, or publicly financed). The biannual CHIS is the largest state health survey conducted in the United States, collecting information from over 40,000 households. More information on CHIS is available at www.chis.ucla.edu.
2. The latest (2006) California Employer Health Benefits Survey is utilized to estimate:
   - size of firm,
   - percentage of firms that are purchased/underwritten (versus self-insured),
   - premiums for plans regulated by the Department of Managed Health Care (DMHC) (primarily health maintenance organizations [HMOs]),
   - premiums for policies regulated by the California Department of Insurance (CDI) (primarily preferred provider organizations [PPOs]), and
   - premiums for high-deductible health plans (HDHP) for the California population covered under employment-based health insurance.

   This annual survey is released by the California Health Care Foundation/Center for Studying Health System Change (CHCF/HSC) and is similar to the national employer survey released annually by the Kaiser Family Foundation and the Center for Studying Health System Change. More information on the CHCF/HSC is available at www.chcf.org/topics/healthinsurance/index.cfm?itemID=127480.

3. Milliman data sources are relied on to estimate the premium impact of mandates. Milliman's projections derive from the Milliman Health Cost Guidelines (HCGs). The HCGs are a health care pricing tool used by many of the major health plans in the United States (see www.milliman.com/expertise/healthcare/products-tools/milliman-care-guidelines/index.php). Most of the data sources underlying the HCGs are claims databases from commercial health insurance plans. The data are supplied by health

insurance companies, Blues plans, HMOs, self-funded employers, and private data vendors. The data are mostly from loosely managed healthcare plans, generally those characterized as preferred provider plans or PPOs. The HCGs currently include claims drawn from plans covering 4.6 million members. In addition to the Milliman HCGs, CHBRP's utilization and cost estimates draw on other data, including the following:

- The MEDSTAT MarketScan Database, which includes demographic information and claim detail data for approximately 13 million members of self-insured and insured group health plans.
- An annual survey of HMO and PPO pricing and claim experience, the most recent survey (2006 Group Health Insurance Survey) contains data from six major California health plans regarding their 2005 experience.
- Ingenix MDR Charge Payment System, which includes information about professional fees paid for healthcare services, based upon approximately 800 million claims from commercial insurance companies HMOs and self-insured health plans.
- These data are reviewed for generalizability by an extended group of experts within Milliman, but are not audited externally.

4. An annual survey by CHBRP of the seven largest providers of health insurance in California (Aetna, Blue Cross of California, Blue Shield of California, CIGNA, Health Net, Kaiser Foundation Health Plan, and PacifiCare) to obtain estimates of baseline enrollment by purchaser (i.e., large and small group and individual) type of plan (i.e., DMHC- or CDI-regulated), cost-sharing arrangements with enrollees and average premiums. Enrollment in these seven firms represents 82% of enrollees in full service health plans regulated by the DMHC and 46% of lives covered by comprehensive health insurance products regulated by the CDI.

Public health insurance

- CalPERS enrollment information was obtained directly from CalPERS and includes 2006 enrollment data.

Caveats and Assumptions

CHBRP's analysis of AB 1214 is based on several key assumptions, some of which apply to both scenarios presented in this report, and others that are unique to each of the scenarios. These assumptions are:

Key assumptions common to scenarios 1 (High Impact) and 2 (Low Impact):

- There are currently 44 benefit mandates in California. AB 1214 would eliminate the requirement that health insurance policies include all these mandated benefits, but the number of possible combinations of these 44 benefits exceeds 17 quadrillion (2 raised to the 44^{th} power). Because it is impossible to determine exactly which combinations of current mandated benefits would be offered under AB 1214, CHBRP developed three prototype insurance policies that would be likely to be offered under AB 1214, one for each of the following market segments: (1) DMHC-regulated group and individual, (2) CDI-regulated group, and (3) CDI-regulated individual. In general, the

DMHC-regulated prototypes included more of the current mandated benefits than the CDI-regulated prototypes. These prototype insurance policies were based on: (1) review of grey literature; (2) review of plans offered in other states with laws that allowed for the development of limited-mandate plans (or plans not subject to state mandates); (3) review of low-premium plans currently offered in California; and (4) discussion with CHBRP's content expert for this report, Melinda Buntin, PhD, health economist at the RAND Corporation.

- The uninsurance rate among adults aged 18 to 64 years and children aged 0 to 17 years who are not eligible for public programs would decline by 1.1% for every 10% drop in premiums in each market segment. The overall price change estimated by CHBRP for all limited-mandate plans will be applied to the estimated 4.445 million uninsured adults and children not eligible for public programs. The number of uninsured was obtained from CHIS 2005. CHBRP was not able to stratify the uninsured who are employed by size of firm. There is some evidence in the research literature that reducing the number of mandated benefits does have a positive impact on the number of insured individuals (Sloan and Conover, 1998; Jensen and Morrisey, 1999).
- The newly insured will be distributed according to the same proportions as in the baseline period. The cost of the uninsured in the baseline period would be about 50% of spending in the post-AB 1214 period for the newly insured, based on estimates from the RAND Health Insurance Experiment data about the impact on expenditures of moving from high-deductible coverage to comprehensive coverage with limited cost sharing (Newhouse, 1993).
- The administrative expenses and profit margins are assumed to be the same for comprehensive, full benefit plans as they are for limited-mandate plans, HDHPs and limited-mandate HDHP plans.

Key assumptions under scenario 1 (high impact):

- This scenario assumes all insurers would offer limited-mandate plans in every market, and all currently insured Californians would purchase the limited-mandate plans instead of their current health insurance products. The purpose of this scenario is to illustrate the maximum savings possible from removing the requirement for mandated benefits in the short term.
- Because premiums for all segments of the market (large-group, small-group, and individual sectors, and DMHC-regulated vs. CDI-regulated) would be lower, CHBRP assumes that the market share of low- and zero-deductible plans relative to HDHPs remains the same within each market segment, even though the price reductions are not exactly the same in each market. This simplifying assumption is supported by evidence from Marquis et al. (2006) that overall demand for insurance is not sensitive to changes in the benefits offered.

Key assumptions under scenario 2 (low impact):

- This scenario assumes that only those who currently have lower-premium plans (i.e., HDHPs) would be interested in purchasing health insurance products with limited

mandates, and that everyone currently with an HDHP would purchase a less-expensive HDHP with limited mandates. In addition, this scenario also accounts for the substitution of some full-benefit products with limited-benefit HDHPs because of the change in relative prices (i.e., premiums) of HDHPs compared to full-benefit plans.

- Because HDHPs with limited mandates have lower premiums than full-benefit HDHPs, the HDHP market share would increase because of this price reduction. According to Marquis et al. (2006), a 20% price reduction results in a 7.5% increase in market share. Therefore, the increase in HDHP market share (and decrease in market share for non-HDHP products) will be determined by the percent premium reduction in limited-benefit HDHPs estimated by CHBRP for each market sector (large-group, small-group, and individual sectors, and DMHC-regulated vs. CDI-regulated).
- The reduction in the number of uninsured will be estimated in the same way as above under scenario 1, but all newly insured will be concentrated in the HDHP market only.

Both scenarios overstate the impact of AB 1214, because not everyone would switch from their current plans to limited-mandate plans. Therefore, these scenarios should be thought of as **upper bounds** in the short term rather than actual estimates of how the market might respond to AB 1214. They are useful because they show **at most** the short-term savings that might be possible if there was broad acceptance of these policies.

APPENDIX E: INFORMATION SUBMITTED BY OUTSIDE PARTIES

In accordance with CHBRP policy to analyze information submitted by outside parties during the first two weeks of the CHBRP review, the following parties chose to submit information:

No information was submitted directly by interested parties for this analysis.

For information on the processes for submitting information to CHBRP for review and consideration please visit www.chbrp.org/requests.html.

APPENDIX F: LIMITED-MANDATE PLAN DESIGNS USED TO MODEL COST IMPACT SCENARIOS

This appendix presents the prototypes for the limited-mandate plans that are used to model the cost impact scenarios presented in this report. For more information regarding the underlying assumption of which benefit *mandates* are included or excluded, please refer to Table F-4: Treatment of Mandates in Current Law for Each of the CDI Limited-Mandate Plan Prototypes, and Table F-5: Treatment of Mandates in Current Law for Each of the DMHC Limited-Mandate Plan Prototype.

The limited-mandate plans designs, and underlying assumptions as to which benefit mandates are included, were based on a review of "summary of benefits" documents or disclosure form for carriers that offered limited-mandate or limited-benefit plans in other states that have laws permitting the development of these plans. Typically these limited-mandate plans may waive or be exempt from all or a subset of benefit mandates in law in those particular states. In addition to these publicly available marketing sources, the grey literature was also consulted. Note that these prototypes do not include cost-sharing information such as the deductible, copayments and out-of-pocket maximums. This is not specified because this Cost Impact analysis assumes that cost sharing would not change as a result of AB 1214 since the bill does not affect related requirements.

Group CDI-Regulated Limited Benefit Policies

The proposed design for a large-group CDI limited-mandate plan could be one that a carrier can present as a lower-premium option to large-group purchasers. Large-group purchasers who offer this policy to their employees would do so in conjunction with another, more comprehensive HMO or PPO policy. The policy is designed to provide large-group employees the option of purchasing a bare bones policy at the lowest cost. The design for a small-group CDI limited-mandate plan is identical to that of the large-group market. It is also designed for small-group purchasers who would want to make available a bare bones policy at the lowest cost. This could be also be used by some small groups to attract better risk. If there is enough premium savings associated with this plan, smaller groups who do not currently offer health insurance may offer this policy. This plan design could also be appropriate for groups that would not offer coverage for dependants.

Table F-1. Large-Group and Small-Group CDI Limited-Mandate Plan

BENEFIT	INCLUDED/ EXCLUDED
Out-of-Pocket Maximum	
Professional Services (Doctor office visits)	
Primary and specialty care visits (includes routine and Urgent Care appointments)	Included
Preventive screening	Included
Well-child preventive care visits (0-23 months)	Included
Family planning visits	Excluded
Scheduled prenatal care and first postpartum visit	Included
Eye exams	Excluded
Hearing tests	Excluded
Physical, occupational, and speech therapy visits	Included
Outpatient Services	
Outpatient surgery	Included
Vaccines (immunizations)	Included
X-rays and lab tests	Included
Health education	Excluded
Hospitalization Services	
Room and board, surgery, anesthesia, X-rays, lab tests, and drugs	Included
Labor & Delivery	Included
Emergency Department visits	Included
Ambulance Services	Included
Prescription Drug Coverage	
Generic	Included
Brand name	Excluded
Contraception drugs and devices	Excluded
Durable Medical Equipment	Excluded
Prosthetics and Orthotics	Excluded
Mental Health Services	
Inpatient psychiatric care	Excluded
Outpatient visits	Excluded
Chemical Dependency Services	
Inpatient detoxification	Excluded
Outpatient visits	Excluded
Home Health Services	Excluded
Non-custodial skilled nursing facility care	Included
Hospice care	Excluded
Infertility services	Excluded
Acupuncture	Excluded
Chiropractic	Excluded
Other (dental procedures, TMJ, experimental or investigational treatment, cosmetic surgery, food and dietary supplements, hearing aid, over-the-counter drugs or devices, weight reduction, sexual reassignment surgery)	Excluded

Individual CDI-Regulated Limited-Mandate Plan

This plan is designed for young healthy adults who cannot necessarily afford a comprehensive HMO or PPO option. It would provide catastrophic coverage and provide only those preventive services recommended for adults. It is not designed to carry children as dependants. Note that the main difference between this individual plan design and the plan design for CDI large and small groups is its lack of maternity coverage.

Table F-2. Individual CDI Limited-Mandate Plan

BENEFIT	INCLUDED/ EXCLUDED
Out-of-Pocket Maximum	
Professional Services (Doctor office visits)	
Primary and specialty care visits (includes routine and Urgent Care appointments)	Included
Preventive screening	Included
Well-child preventive care visits (0-23 months)	Excluded
Family planning visits	Excluded
Scheduled prenatal care and first postpartum visit	Excluded
Eye exams	Excluded
Hearing tests	Excluded
Physical, occupational, and speech therapy visits	Included
Outpatient Services	
Outpatient surgery	Included
Vaccines (immunizations)	Included
X-rays and lab tests	Included
Health education	Excluded
Hospitalization Services	
Room and board, surgery, anesthesia, X-rays, lab tests, and drugs	Included
Labor & Delivery	Excluded
Emergency Department visits	Included
Ambulance Services	Included
Prescription Drug Coverage	
Generic	Included
Brand name	Excluded
Contraception drugs and devices	Excluded
Durable Medical Equipment	Excluded
Prosthetics and Orthotics	Excluded
Mental Health Services	
Inpatient psychiatric care	Excluded
Outpatient visits	Excluded
Chemical Dependency Services	
Inpatient detoxification	Excluded
Outpatient visits	Excluded
Home Health Services	Excluded
Non-custodial skilled nursing facility care	Included
Hospice care	Excluded
Infertility services	Excluded
Acupuncture	Excluded
Chiropractic	Excluded
Other (dental procedures, TMJ, experimental or investigational treatment, cosmetic surgery, food and dietary supplements, hearing aid, over-the-counter drugs or devices, weight reduction, sexual reassignment surgery)	Excluded

DMHC Limited-Mandate Plan

Following the passage of AB 1214, DMHC-regulated plans would still be required to provide all "basic health care services." In addition, AB 1214 would not diminish the DMHC's authority to review and approve all health plan designs prior to marketing. This would limit carriers' ability to offer plans with waived mandated benefits. This plan is designed to provide large- and small-group employees and individuals the option of purchasing a bare bones policy at the lowest cost and for those groups who may otherwise not offer coverage for dependants. This could be attractive to those who would prefer an HMO option.

Table F-3. Group and Individual DMHC Limited-Mandate Plan

BENEFIT	INCLUDED/ EXCLUDED
Out-of-Pocket Maximum	
Professional Services (Doctor office visits)	
Primary and specialty care visits (includes routine and Urgent Care appointments)	Included
Preventive screening	Included
Well-child preventive care visits (0-23 months)	Included
Family planning visits	Excluded
Scheduled prenatal care and first postpartum visit	Included
Eye exams	Excluded
Hearing tests	Excluded
Physical, occupational, and speech therapy visits	Included
Outpatient Services	
Outpatient surgery	Included
Vaccines (immunizations)	Included
X-rays and lab tests	Included
Health education	Excluded
Hospitalization Services	
Room and board, surgery, anesthesia, X-rays, lab tests, and drugs	Included
Labor & Delivery	Included
Emergency Department visits	Included
Ambulance Services	Included
Prescription Drug Coverage	
Generic	Included
Brand name	Included
Contraception drugs and devices	Excluded
Durable Medical Equipment	Excluded
Prosthetics and Orthotics	Excluded
Mental Health Services	
Inpatient psychiatric care	Included
Outpatient visits	Included
Chemical Dependency Services	
Inpatient detoxification	Excluded
Outpatient visits	Excluded
Home Health Services	Included
Non-custodial skilled nursing facility care	Included
Hospice care	Included
Infertility services	Excluded
Acupuncture	Excluded
Chiropractic	Excluded
Other (dental procedures, TMJ, experimental or investigational treatment, cosmetic surgery, food and dietary supplements, hearing aid, over-the-counter drugs or devices, weight reduction, sexual reassignment surgery)	Excluded

Table F-4. Treatment of Mandates in Current Law for Each of the CDI-Regulated Limited-Mandated Plan Prototypes

A. Cancer Screening & Treatment

Description of Benefit	**Health & Safety Code Section**	**California Insurance Code Section**	**Type of Requirement Mandate or Mandated Offering**	**Markets Affected**	**CDI Individual** N/A=mandate doesn't apply	**CDI Group** N/A=mandate doesn't apply
Cancer screening tests	1367.665	10123.2	Mandate	Individual and group	Included as part of preventive services	Included as part of preventive services
Prostate cancer screening and diagnosis	1367.64	10123.83	Mandate	Individual and group	Included as part of preventive services	Included as part of preventive services
Cervical cancer screening	1367.66	10123.18	Mandate	Individual and group	Included as part of preventive services	Included as part of preventive services
Breast cancer screening, diagnosis, and treatment	1367.6	10123.8	Mandate	No mention	Included	Included
Breast cancer screening with Mammography	1367.65	10123.81	Mandate	No mention	Included as part of preventive services	Included as part of preventive services
Mastectomy and lymph node dissection – length of stay	1367.635	10123.86	Mandate	Individual and group	Included under ambulatory care or inpatient services	Included under ambulatory or inpatient services
Patient care related to clinical trials for cancer	1370.6	N/A	Mandate	No mention	N/A	N/A

B. Chronic Conditions

Description of Benefit	**Health & Safety Code Section**	**California Insurance Code Section**	**Type of Requirement Mandate or Mandated Offering**	**Markets Affected**	**CDI Individual** N/A=mandate doesn't apply	**CDI Group** N/A=mandate doesn't apply
Diabetes management and treatment	1367.51	10176.61	Mandate	No mention	Included	Included
Osteoporosis diagnosis, treatment and management	1367.67	10123.185	Mandate	No mention	Included	Included
Transplantation services for persons with HIV	1374.17	10123.21	Mandate	No mention	Included under inpatient services	Included under inpatient services
AIDS vaccine	1367.45	10145.2	Mandate	Individual and group	Excluded	Excluded
Phenylketonuria	1374.56	10123.89	Mandate	No mention	Excluded as part of maternity services	Included as part of maternity services

C. Mental Illness

Description of Benefit	**Health & Safety Code Section**	**California Insurance Code Section**	**Type of Requirement Mandate or Mandated Offering**	**Markets Affected**	**CDI Individual** N/A=mandate doesn't apply	**CDI Group** N/A=mandate doesn't apply
Coverage for mental and nervous disorders	N/A	10125	Mandated offering	Group	N/A	Excluded
Coverage and premiums for persons with physical or mental impairment	1367.8	10122.1	Mandate	Individual and group	Excluded under mental health services	Excluded under mental health services
Parity in coverage for severe mental illness	1374.72	10123.15 (10144.5)	Mandate	Group	N/A	Excluded under mental health services
Alcoholism treatment	1367.2	10123.6	Mandated offering	Group	N/A	Excluded under chemical dependency services

D. Orthotics and Prosthetics

Description of Benefit	Health & Safety Code Section	California Insurance Code Section	Type of Requirement Mandate or Mandated Offering	Markets Affected	CDI Individual N/A=mandate doesn't apply	CDI Group N/A=mandate doesn't apply
Orthotic and prosthetic devices and services	1367.18	10123.7	Mandated offering	Group	N/A	Excluded
Prosthetic devices for laryngectomy	1367.61	10123.82	Mandate	No mention	Excluded	Excluded
Special footwear for persons suffering from foot disfigurement	1367.19	10123.141	Mandated offering	No mention	Excluded as orthotic and prosthetic items and devices	Excluded as orthotic and prosthetic items and devices

E. Pain Management

Description of Benefit	Health & Safety Code Section	California Insurance Code Section	Type of Requirement Mandate or Mandated Offering	Markets Affected	CDI Individual N/A=mandate doesn't apply	CDI Group N/A=mandate doesn't apply
Acupuncture	N/A	10127.3	Mandated offering	Group	N/A	Excluded
Pain management medication for terminally ill	1367.215	N/A	Mandate	No mention	N/A	N/A
General anesthesia for dental procedures	1367.71	10119.9	Mandate	No mention	Excluded	Excluded

F. Pediatric Health

Description of Benefit	**Health & Safety Code Section**	**California Insurance Code Section**	**Type of Requirement Mandate or Mandated Offering**	**Markets Affected**	**CDI Individual** N/A=mandate doesn't apply	**CDI Group** N/A=mandate doesn't apply
Comprehensive preventive care for children aged 16 years or younger	1367.3	10123.55	Mandated offering	Group	N/A [excluded under preventive services]	Included as part of preventive services
Comprehensive preventive care for children aged 17 or 18 years	1367.3	10123.55	Mandated offering	Group	N/A [excluded under preventive services]	Included as part of preventive services
Asthma management	1367.06	N/A	Mandate	No mention	N/A	N/A
Screening children for blood lead levels	1367.3 (b)(2)(D)	10119.8	Mandate	Individual and group	Excluded under preventive services	Included as part of preventive services

G. Reproductive

Description of Benefit	**Health & Safety Code Section**	**California Insurance Code Section**	**Type of Requirement Mandate or Mandated Offering**	**Markets Affected**	**CDI Individual** N/A=mandate doesn't apply	**CDI Group** N/A=mandate doesn't apply
Contraceptive devices requiring a prescription	1367.25	10123.196	Mandate	No mention	Excluded	Excluded
Infertility treatments	1374.55	10119.6	Mandated offering	Group	N/A	Excluded
Conditions associated with exposure to diethylstilbestrol	1367.9	10119.7	Mandate	No mention	Excluded	Excluded
Prenatal diagnosis of genetic disorders	1367.7	10123.9	Mandated offering	Group	N/A	Included under maternity services
Expanded alpha-fetoprotein	1367.54	10123.184	Mandate	Individual and group	Excluded	Included as part of maternity services
Maternity benefits – minimum length of stay[42]	1367.62	10123.87	Mandate	Individual and group	Excluded	Included under maternity services
Maternity coverage – amount of copayment or deductible for inpatient services	1373.4	N/A	Mandate	No mention	N/A	N/A

[42] The federal Newborns' and Mothers' Health Protection Act of 1996 requires coverage for a minimum length of stay following delivery *if* the plan covers maternity service.

H. Mandates related to Surgery

Description of Benefit	Health & Safety Code Section	California Insurance Code Section	Type of Requirement Mandate or Mandated Offering	Markets Affected	CDI Individual N/A=mandate doesn't apply	CDI Group N/A=mandate doesn't apply
Jawbone or associated bone joints	1367.68	10123.21	Mandate	No mention	Excluded under TMJ and dental disorders	Excluded under TMJ and dental disorders
Reconstructive surgery[43]	1367.63	10123.88	Mandate	Individ-ual and group	Included (federal)	Included (federal)

I. Hospice and Home Health Care Benefit Mandates

Description of Benefit	Health & Safety Code Section	California Insurance Code Section	Type of Requirement (Mandate or Mandated Offering)	Markets Affected	CDI Individual LBP N/A=mandate doesn't apply	CDI Small Group LBP N/A=mandate doesn't apply
Hospice care	1368.2	N/A	Mandate	Group	N/A	N/A
Home health care	N/A	10123.10	Mandated offering	Group	N/A	Excluded

[43] The federal Women's Health and Cancer Rights Act requires coverage for postmastectomy reconstructive surgery so that service would still have to be covered, even if this mandate were to be waived.

J. Other Mandates Regarding Terms and Conditions of Coverage

Description of Benefit	Health & Safety Code Section	California Insurance Code Section	Type of Requirement (Mandate or Mandated Offering)	Markets Affected	CDI Individual LBP N/A=mandate doesn't apply	CDI Small Group LBP N/A=mandate doesn't apply
Prescription drugs: coverage of "off-label" use	1367.21	10123.195	Mandate	No mention	Excluded	Excluded
Prescription drugs: coverage for previously prescribed drugs	1367.22	N/A	Mandate	No mention	N/A	N/A
Authorization for nonformulary prescription drugs	1367.24	N/A	Mandate	No mention	N/A	N/A
Coverage for persons with blindness or partial blindness	1367.4	N/A	Mandate	Individual and group	N/A	N/A

K. Other Provider Mandates

Description of Benefit	Health & Safety Code Section	California Insurance Code Section	Type of Requirement (Mandate or Mandated Offering)	Markets Affected	CDI Individual LBP N/A=mandate doesn't apply	CDI Small Group LBP N/A=mandate doesn't apply
Medical transportation services – direct reimbursement	1367.11	10126.6	Mandate	No mention	Included under ambulance services	Included under ambulance services
OB-GYNs as primary care providers	1367.69	10123.83	Mandate	No mention	Included	Included
Pharmacists – compensation for services within their scope of practice	1368.5	N/A	Mandate	No mention	N/A	N/A

As indicated in Table F-3, only one prototype was used for the DMHC-regulated market. However, not all mandates apply to the individual market. Therefore, if a mandate only applied to the group market and was considered excluded in the group market, it was also considered excluded in the individual market.

Table F-5. Treatment of Mandates in Current Law for the DMHC Limited-Mandate Plan Prototype

A. Cancer Screening & Treatment

Description of Benefit	**Health & Safety Code Section**	**California Insurance Code Section**	**Type of Requirement Mandate or Mandated Offering**	**Markets Affected**	**DMHC Individual** N/A=mandate doesn't apply	**DMHC Small and Large Group** N/A=mandate doesn't apply
Cancer screening tests	1367.665	10123.2	Mandate	Individual and group	Included as part of preventive services	Included as part of preventive services
Prostate cancer screening and diagnosis	1367.64	10123.83	Mandate	Individual and group	Included as part of preventive services	Included as part of preventive services
Cervical cancer screening	1367.66	10123.18	Mandate	Individual and group	Included as part of preventive services	Included as part of preventive services
Breast cancer screening, diagnosis, and treatment	1367.6	10123.8	Mandate	No mention	Included	Included
Breast cancer screening with Mammography	1367.65	10123.81	Mandate	No mention	Included as part of preventive services	Included as part of preventive services
Mastectomy and lymph node dissection – length of stay	1367.635	10123.86	Mandate	Individual and group	Included under ambulatory care or inpatient services	Included under ambulatory or inpatient services
Patient care related to clinical trials for cancer	1370.6	N/A	Mandate	No mention	Excluded	Excluded

B. Chronic Conditions

Description of Benefit	**Health & Safety Code Section**	**California Insurance Code Section**	**Type of Requirement Mandate or Mandated Offering**	**Markets Affected**	**DMHC Individual** N/A=mandate doesn't apply	**DMHC Small and Large Group** N/A=mandate doesn't apply
Diabetes management and treatment	1367.51	10176.61	Mandate	No mention	Included	Included
Osteoporosis diagnosis treatment and management	1367.67	10123.185	Mandate	No mention	Included	Included
Transplantation services for persons with HIV	1374.17	10123.21	Mandate	No mention	Included under inpatient services	Included under inpatient services
AIDS vaccine	1367.45	10145.2	Mandate	Individual and group	Excluded	Excluded
Phenylketonuria	1374.56	10123.89	Mandate	No mention	Included as part of maternity services	Included as part of maternity services

C. Mental Illness

Description of Benefit	**Health & Safety Code Section**	**California Insurance Code Section**	**Type of Requirement Mandate or Mandated Offering**	**Markets Affected**	**DMHC Individual** N/A=mandate doesn't apply	**DMHC Small and Large Group** N/A=mandate doesn't apply
Coverage for mental and nervous disorders	N/A	10125	Mandated offering	Group	N/A	N/A
Coverage and premiums for persons with physical or mental impairment	1367.8	10122.1	Mandate	Individual and group	Included under mental health services (SMI only with limits)	Included under mental health services (SMI only with limits)
Parity in coverage for severe mental illness	1374.72	10123.15 (10144.5)	Mandate	Group	Included under mental health services (SMI only with limits)	Included under mental health services (SMI only with limits)
Alcoholism treatment	1367.2	10123.6	Mandated offering	Group	N/A	Excluded under chemical dependency services

D. Orthotics and Prosthetics

Description of Benefit	**Health & Safety Code Section**	**California Insurance Code Section**	**Type of Requirement Mandate or Mandated Offering**	**Markets Affected**	**DMHC Individual** N/A=mandate doesn't apply	**DMHC Small and Large Group** N/A=mandate doesn't apply
Orthotic and prosthetic devices and services	1367.18	10123.7	Mandated offering	Group	N/A	Excluded
Prosthetic devices for laryngectomy	1367.61	10123.82	Mandate	No mention	Excluded	Included
Special footwear for persons suffering from foot disfigurement	1367.19	10123.141	Mandated offering	No mention	Excluded as orthotic and prosthetic items and devices	Excluded as orthotic and prosthetic items and devices

E. Pain Management

Description of Benefit	**Health & Safety Code Section**	**California Insurance Code Section**	**Type of Requirement Mandate or Mandated Offering**	**Markets Affected**	**DMHC Individual** N/A=mandate doesn't apply	**DMHC Small and Large Group** N/A=mandate doesn't apply
Acupuncture	N/A	10127.3	Mandated offering	Group	N/A	Excluded
Pain management medication for terminally ill	1367.215	N/A	Mandate	No mention	Included	Included
General anesthesia for dental procedures	1367.71	10119.9	Mandate	No mention	Excluded	Included

F. Pediatric Health

Description of Benefit	**Health & Safety Code Section**	**California Insurance Code Section**	**Type of Requirement Mandate or Mandated Offering**	**Markets Affected**	**DMHC Individual** N/A=mandate doesn't apply	**DMHC Small and Large Group** N/A=mandate doesn't apply
Comprehensive preventive care for children aged 16 years or younger	1367.35	10123.5	Mandate	Group	N/A	Included
Comprehensive preventive care for children aged 17 or 18 years	1367.3	10123.55	Mandated offering	Group	N/A	Included
Asthma management	1367.06	N/A[44]	Mandate	No mention	Included	Included
Screening children for blood lead levels	1367.3(b)(2)(D)	10119.8	Mandate	Individual and group	Included	Included

[44] An N/A in either the Health & Safety Code column or the California Insurance Code column indicates that a mandate does not apply to plans covered under that code.

G. Reproductive

Description of Benefit	Health & Safety Code Section	California Insurance Code Section	Type of Requirement Mandate or Mandated Offering	Markets Affected	DMHC Individual N/A=mandate doesn't apply	DMHC Small and Large Group N/A=mandate doesn't apply
Contraceptive devices requiring a prescription	1367.25	10123.196	Mandate	No mention	Excluded	Excluded
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Expanded alpha-fetoprotein	1367.54	10123.184	Mandate	Individual and group	Included as part of maternity services	Included as part of maternity services
Maternity benefits – minimum length of stay[45]	1367.62	10123.87	Mandate	Individual and group	Included under maternity services	Included under maternity services
Maternity coverage – amount of copayment or deductible for inpatient services	1373.4	N/A	Mandate	No mention	Included [plan prototypes did not vary cost-sharing.]	Included[plan prototypes did not vary cost-sharing.]

[45] The federal Newborns' and Mothers' Health Protection Act of 1996 requires coverage for a minimum length of stay following delivery *if* the plan covers maternity service.

H. Mandates related to Surgery

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Reconstructive surgery[46]	1367.63	10123.88	Mandate	Individual and group	Included (federal)	Included (federal)

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Description of Benefit	Health & Safety Code Section	California Insurance Code Section	Type of Requirement Mandate or Mandated Offering	Markets Affected	DMHC Individual N/A=mandate doesn't apply	DMHC Small and Large Group N/A=mandate doesn't apply
Hospice care	1368.2	N/A	Mandate	Group	N/A	Included
Home health care	N/A	10123.10	Mandated offering	Group	N/A	N/A

[46] The federal Women's Health and Cancer Rights Act requires coverage for postmastectomy reconstructive surgery so that service would still have to be covered, even if this mandate were to be waived.

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Description of Benefit	Health & Safety Code Section	California Insurance Code Section	Type of Requirement Mandate or Mandated Offering	Markets Affected	DMHC Individual N/A=mandate doesn't apply	DMHC Small and Large Group N/A=mandate doesn't apply
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Prescription drugs: coverage for previously prescribed drugs	1367.22	N/A	Mandate	No mention	Excluded	Included
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OB-GYNs as primary care providers	1367.69	10123.83	Mandate	No mention	Included	Included
Pharmacists – compensation for services within their scope of practice	1368.5	N/A	Mandate	No mention	Included	Included

ACKNOWLEDGEMENTS

Janet Coffman, MPP, PhD, Miki Hong, MPH, Wade Aubry, MD, and Edward Yelin, PhD, all of the University of California, San Francisco, conducted the medical effectiveness analysis. Wayne Dysinger, MD, MPH, of Loma Linda University and Ted Ganiats, MD, of the University of California, San Diego provided input on the medical effectiveness analysis of the preventive services benefit mandates. Susan Ettner, PhD, of University of California, Los Angeles provided input on the medical effectiveness analysis of mental health and substance abuse benefit mandates and Michael Cabana, MD, of the University of California, San Francisco provided input on the medical effectiveness analysis of the pediatric asthma mandate. Steve Clancy, MLIS, of the University of California, Irvine, Penny Coppernoll-Blach, MLIS, of the University of California, San Diego, and Min-Lin Fang, MLIS, of the University of California, San Francisco, conducted the literature search. Melinda Beeuwkes Buntin, PhD, of RAND Inc., provided technical assistance and expert input on the analytic approach. Helen Halpin, PhD, of the University of California, Berkeley, and Susan Philip, MPP of CHBRP staff prepared the literature analysis on consumers' ability to use information to make informed health care coverage decisions. Sara McMenamin, MPH, PhD, and Helen Halpin, PhD, both of the University of California, Berkeley, prepared the public health impact analysis. Gerald Kominski, PhD, and Nadereh Pourat, PhD, of the University of California, Los Angeles, prepared the cost impact analysis. Jay Ripps, FSA, MAAA, of Milliman, Inc., provided actuarial analysis. Susan Philip, MPP, and Cynthia Robinson, MPP, of CHBRP staff prepared the Introduction and synthesized the individual sections into a single report. Sarah Ordódy, BA, provided editing services. A subcommittee of CHBRP's National Advisory Council (see final pages of this report) and two members of the CHBRP Faculty Task Force—Harold Luft, PhD, of the University of California, San Francisco, and Thomas MaCurdy, PhD, of Stanford University—reviewed the analysis for its accuracy, completeness, clarity, and responsiveness to the Legislature's request.

CHBRP gratefully acknowledges all of these contributions but assumes full responsibility for all of the report and its contents. Please direct any questions concerning this report to:

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As required by the CHBRP authorizing legislation, UC contracts with a certified actuary, Milliman Inc. (Milliman), to assist in assessing the financial impact of each benefit mandate bill. Milliman also helped with the initial development of CHBRP methods for assessing that impact.

The **National Advisory Council** provides expert reviews of draft analyses and offers general guidance on the program to CHBRP staff and the Faculty Task Force. CHBRP is grateful for the valuable assistance and thoughtful critiques provided by the members of the National Advisory Council. However, the Council does not necessarily approve or disapprove of or endorse this report. CHBRP assumes full responsibility for the report and the accuracy of its contents.

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