



Medical Device Legislative Tracking Chart

Bill #	Author/Sponsor	Companion	Tag	Summary	Status/Date
HB 806	Gallego		Relating to health benefit plan coverage for certain prosthetic devices, orthotic devices, and related services.	As Finally Passed: Adds Chapter 1371: Coverage for Certain Prosthetic Devices, Orthotic Devices, and Related Services to the Insurance Code. Requires health benefit plans to provide coverage for prosthetic devices, orthotic devices, and professional services related to the fitting/use of those devices equal to that under federal law coverage for the aged and disabled. Limits benefits to the most appropriate model of device adequately meeting needs. Repair/replacement is a covered benefit unless necessitated by misuse/loss by enrollee. Coverage must be in a manner appropriate, may be subject to deductibles/copays/coinsurance, and may not be subject to annual dollar limits. Covered benefits may be provided by a pharmacy qualified to bill. May require prior authorization. manage care plan coverage may be covered only if devices are provided by a vendor/provider that contracts with benefit plan provider.	09-01-09 G Earliest effective date
HB 852	Todd Smith	SB 353 by Shapleigh	Relating to nonpayment of hospitals under the state Medicaid program for certain preventable adverse conditions.	As Substituted: Adds Section 32.02805: Nonpayment of Hospitals for Preventable Adverse Conditions to the Human Resources Code. Prohibits DSHS/HHSC from paying additional payments to hospitals for preventable adverse conditions acquired by medical assistance patients during hospitalization. List includes: foreign objects retained after surgery, surgery on wrong body part, surgery on wrong person, intravascular air embolism, blood/blood product incompatibility, stage 3 or 4 pressure ulcer, fall/trauma resulting in fracture/dislocation/intracranial injury/crushing injury, burn/electric shock, catheter-associated UT infection, vascular catheter-associated infection, poor glycemic control, surgical site infections, and deep vein thrombosis/pulmonary embolism following orthotic procedures. Allows HHSC Commissioner to adopt rules for additional events. Nonpayment does not create civil liability and is not subject to discover/admissible in civil actions. Requires compilation of data by HHSC and publishing of statistical information on website.	05-14-09 H Set on the House Calendar *Reporting of Preventable Adverse Events added to SB 203
HB 1487	Pitts	SB 1881 by Nelson	Relating to the alignment of certain Medicaid procedures regarding written orders	As Finally Passed: Amends Chapter 531 of the Government Code to require HHSC to review forms/requirements under Medicaid regarding written orders/procedures for diabetic equipment/supplies compared to Medicare. HHSC is required to modify rules where applicable to provide an ordering system under Medicaid comparable to the ordering system for diabetic equipment/supplies under Medicare. System must permit diabetic equipment or supplies supplier to complete forms by hand/enter electronically medical information/orders to provide information to dispense diabetic equipment/supplies. Providers may bill and collect payment	5-26-09 Sent to the Governor



Medical Device Legislative Tracking Chart

			for diabetic equipment and supplies with comparable Medicare written order procedures.	for services if provider has a copy of the required form signed by a medical practitioner licensed to treat diabetic patients in TX.	
HB 1740	Donna Howard		Relating to the authorization of physicians and therapeutic optometrists to dispense therapeutic contact lenses.	As Finally Passed: Amends Section 551.003 of the Occupations Code to define therapeutic contact lens. Amends Section 551.004 of the Occupations Code to state it does not prevent a physician or therapeutic optometrist from dispensing and charging for therapeutic contact lenses. Section does not authorize a therapeutic optometrist to prescribe, administer, or dispense a drug outside scope of practice.	5-26-09 Sent to Governor
HB 2384	Kolkhorst	SB 527 by Nelson	Relating to certain mammography systems that fail certification standards.	Amends Section 401.430(f) of the Health and Safety Code to require facilities with mammography systems failing to meet certification standards to notify each patient a mammogram was performed on during the period of time when the system failed to meet standards. Requires facility to recommend the patient consult with their physician regarding the need for another mammogram.	See SB 527
HB 3233	John Davis	SB 1535 by Hinojosa	Relating to nonpayment of hospitals under the state Medicaid program for certain preventable adverse events and to the reporting of	Adds Section 32.02805: Nonpayment of Hospitals for Preventable Adverse Events to the Human Resources Code. Defines: infant, serious disability, and serious injury. Requires HHSC to prevent payment to hospitals for preventable adverse events. Defines preventable adverse events as among others, death or disability caused by the use of a contaminated drug/device/biologic if contamination is result of a generally detectable contaminant; death/disability caused by a device during recipient's care used for unintended function; and death/disability caused by medication error. Allows adoption of rules to define additional preventable adverse events. Nonpayment does not create civil liability. Prevents charging client for denied payment. Amends Chapter 98 of the Health and Safety Code to include preventable adverse events in reporting and on advisory panel. Reporting requirement. Information is to be compiled and made publicly available.	04-21-09 H Committee action pending House Public Health *Reporting of Preventable



Medical Device Legislative Tracking Chart

			occurrences of those events at certain health care facilities.		<u>Adverse Events added to SB 203</u>
HB 3336	Hopson	SB 1271 by Uresti	Relating to the requirement that an orthodontist or a prosthetist be licensed as a device manufacturer if fabricating or assembling without an order from certain health care professionals.	Amends Chapter 605 of the Occupations Code to exempt person licensed to practice orthotics/prosthetics who measure/design/fabricate/fit/assemble/adjust/service an orthosis/prosthesis from licensure as device manufacturers. Those who fabricate/assemble without an order from a physician/chiropractor/podiatrist are required to be licensed as device manufacturers.	See SB 1271
HB 3694	Laubenberg	SB 1082 by Huffman	Relating to the storage, maintenance, and distribution of mammography medical records.	Allows money in the perpetual care account to additionally be used for storage/maintenance/distribution of mammography medical records and to assure mammography medical records are available to affected patients.	See SB 1082
HB 3753	Donna Howard	SB 1757 by Watson	Relating to a study by the Texas Commission on Environmental Quality of the	Requires TCEQ to study: 1. methods currently used to safely dispose of pharmaceuticals/medical sharps/potentially dangerous medical waste; 2. alternative methods including in other states; and 3. effects on public health and the environment of various methods. Requires commission to solicit input from: pharmaceutical manufacturers, large/small pharmacies, health care providers, hospitals, clinics, USPS, US EPA, etc. Reporting December 1, 2010 including recommendations.	See SB 1757



Medical Device Legislative Tracking Chart

			methods for safely handling and disposing of certain medical waste.		
HB 4290	Smithee	SB 2200 by Duncan	Relating to retrospective utilization review and utilization review to determine the experimental or investigational nature of a health care service.	As Finally Passed: Amends Section 1305 (Workers' Compensation Health Care Networks) of the Insurance Code to redefine an adverse determination. Adds experimental or investigational nature to the definition of an independent review. Eliminates retrospective review throughout section. Amends Section 4201 (Utilization Review and Independent Review) of the Insurance Code to add experimental or investigational to the definition of adverse determination. Redefines utilization review to include retrospective review and systems for prospective/concurrent/retrospective review determining experimental or investigational nature of services. Requires utilization review agents to provide notice of an adverse determination under retrospective utilization review in writing to provider and patient within 30 days of receipt of claim. Period can be extended by up to 15 days under certain circumstances. Utilization review agents must comply with independent review organization determination regarding experimental/investigational nature of services. Amends the Labor Code (General Provisions under Workers' Compensation) to redefine retrospective review as the utilization review process of medical necessity and reasonableness of care provided to injured employee. Amends Section 408 (Workers' Compensation Benefits) of the Labor Code to eliminate retrospective review. Repealer language.	6-03-09 Sent to the Governor
SB 353	Shapleigh	HB 852 by Todd Smith	Relating to nonpayment of hospitals under the state Medicaid program for certain preventable adverse conditions.	Adds Section 32.02805: Nonpayment of Hospitals for Preventable Adverse Conditions to the Human Resources Code. Prohibits DSHS/HHSC from paying hospitals for preventable adverse conditions acquired by patients during hospitalization. List includes: foreign objects retained after surgery, intravascular air embolism, blood/blood product incompatibility, stage 3 or 4 pressure ulcer, fall/trauma resulting in fracture/dislocation/intracranial injury/crushing injury, burn/electric shock, catheter-associated UT infection, vascular catheter-associated infection, poor glycemic control, surgical site infections, and deep vein thrombosis/pulmonary embolism following orthotic procedures. Nonpayment does not create civil liability and is not subject to discover/admissible in civil actions. Requires compilation of data by HHSC.	02-17-09 S Introduced and referred to committee on Senate Health and Human Services *Reporting



Medical Device Legislative Tracking Chart

					<u>of Preventable Adverse Events added to SB 203</u>
SB 527	Nelson	HB 2384 by Kolkhorst	Relating to certain mammography systems that fail certification standards.	Amends Section 401.430(f) of the Health and Safety Code to require facilities with mammography systems failing to meet certification standards to notify each patient a mammogram was performed on during the period of time when the system failed to meet standards. Requires facility to recommend the patient consult with their physician regarding the need for another mammogram.	05-22-09 G Sent to the Governor
SB 1082	Huffman	HB 3694 by Laubenberg	Relating to the storage, maintenance, and distribution of mammography medical records.	Allows money in the perpetual care account to additionally be used for storage/maintenance/distribution of mammography medical records and to assure mammography medical records are available to affected patients.	5-29-09 Sent to Governor
SB 1271	Uresti	HB 3336 by Hopson	Relating to the requirement that an orthodontist or a prosthetist be licensed as a device manufacturer if fabricating or assembling without an order from certain health	Amends Chapter 605 of the Occupations Code to exempt person licensed to practice orthotics/prosthetics who measure/design/fabricate/fit/assemble/adjust/service an orthosis/prosthesis from licensure as device manufacturers. Those who fabricate/assemble without an order from a physician/chiropractor/podiatrist are required to be licensed as device manufacturers.	5-27-09 Earliest Effective Date



Medical Device Legislative Tracking Chart

			care professionals.		
SB 1535	Hinojosa	HB 3233 by John Davis	Relating to nonpayment of hospitals under the state Medicaid program for certain preventable adverse events and to the reporting of occurrences of those events at certain health care facilities.	Adds Section 32.02805: Nonpayment of Hospitals for Preventable Adverse Events to the Human Resources Code. Defines: infant, serious disability, and serious injury. Requires HHSC to prevent payment to hospitals for preventable adverse events. Defines preventable adverse events as among others, death or disability caused by the use of a contaminated drug/device/biologic if contamination is result of a generally detectable contaminant; death/disability caused by a device during recipient's care used for unintended function; and death/disability caused by medication error. Allows adoption of rules to define additional preventable adverse events. Nonpayment does not create civil liability. Prevents charging client for denied payment. Amends Chapter 98 of the Health and Safety Code to include preventable adverse events in reporting and on advisory panel. Reporting requirement. Information is to be compiled and made publicly available.	03-17-09 S Introduced and referred to committee on Senate Health and Human Services <u>*Reporting of Preventable Adverse Events added to SB 203</u>
SB 1757	Watson	HB 3753 by Donna Howard	Relating to a study by the Texas Commission on Environmental Quality of the methods for safely handling and disposing of certain medical waste.	As Finally Passed: Requires TCEQ to study and make recommendations regarding methods used by consumers, health care providers for disposing of unused pharmaceuticals. TCEQ must consider: 1. methods currently used; 2. alternative methods including in other states; and 3. effects on public health and the environment of various methods. Requires commission to solicit input from: HHSC, DPS, pharmaceutical manufacturers, pharmacies, health care providers, hospitals, clinics, LTC facilities, medical waste processing and handling, solid waste management service providers, local governments, ranchers and farmers, end users of meds, water utilities and other water suppliers USPS, US EPA, etc. Reporting December 1, 2010 including recommendations. Report must include recommendations regarding methods to be used and an analysis of feasibility of implementing methods statewide.	6-03-09 Sent to Governor
SB 1881	Nelson	HB 1487 by Pitts	Relating to the alignment of	Amends Chapter 531 of the Government Code to require HHSC to review forms/requirements under Medicaid regarding written orders/procedures for diabetic equipment/supplies compared	See HB 1487



Medical Device Legislative Tracking Chart

			certain Medicaid procedures regarding written orders for diabetic equipment and supplies with comparable Medicare written order procedures.	to Medicare. HHSC is required to modify rules where applicable to provide an ordering system under Medicaid comparable to the ordering system for diabetic equipment/supplies under Medicare. The following are allowed to complete forms by hand/enter electronically medical information/orders to provide information to dispense diabetic equipment/supplies: physician/PA/nurse practitioner/clinical nurse specialist/provider of diabetic equipment/supplies/staff member or employee designated. Providers may bill and collect payment for services if provider has a copy of the required form signed by a medical practitioner licensed to treat diabetic patients.	
SB 2200	Duncan	HB 4290 by Smithee	Relating to retrospective utilization review and utilization review to determine the experimental or investigational nature of a health care service.	Amends Section 1305 (Workers' Compensation Health Care Networks) of the Insurance Code to redefine an adverse determination. Adds experimental or investigational nature to the definition of an independent review. Eliminates retrospective review throughout section. Amends Section 4201 (Utilization Review and Independent Review) of the Insurance Code to add experimental or investigational to the definition of adverse determination. Redefines utilization review to include retrospective review and systems for prospective/concurrent/retrospective review determining experimental or investigational nature of services. Requires utilization review agents to comply with independent review organization determination regarding experimental/investigational nature of services. Amends the Labor Code (General Provisions under Workers' Compensation) to redefine retrospective review as the utilization review process of medical necessity and reasonableness of care provided to injured employee. Amends Section 408 (Workers' Compensation Benefits) of the Labor Code to eliminate retrospective review. Repealer language.	See HB 4290
HB 97	Fred Brown		Relating to the membership and operation of the State Board of Pharmacy.	Amends Sections 552.004, 552.013, and 553.005 to prohibit persons who are involved in state/federal government entities regulating drugs/medical devices from serving on the State Board of Pharmacy. Amends Section 555.0015 to prohibit disclosure of license holder information to state/federal government without a subpoena/warrant/court order. Adds Section 556.057 requiring the TSBP to develop/implement an inspection schedule of license holders.	02-27-09 H Meeting cancelled for 03/03/09 House Public



Medical Device Legislative Tracking Chart

					Health
HB 142	McClendon	SB 188 by Deuell	Relating to disease control programs to reduce the risk of certain communicable diseases.	<p>Adds Subchapter J:PROGRAMS TO REDUCE RISK OF CERTAIN COMMUNICABLE DISEASES to Chapter 81 of the Health and Safety Code. Allows local health authorities to establish disease control program that: 1. provides for anonymous exchange of used hypodermic needles/syringes for equal number of new ones; 2. offers education on transmission/prevention of communicable diseases; and 3. assists participants in obtaining health-related services including substance abuse treatment and disease testing. Can charge participants a fee for each needle/syringe used in program of not more than 150% of its actual cost. Annual reporting requirement to DSHS. Allows licensed wholesale drug distributors or device distributors to distribute hypodermic needles/syringes to these programs.</p> <p>Sets storage requirements</p> <p>Amends Section 481.125 of the Health and Safety Code (OFFENSE: POSSESSION OR DELIVERY OF DRUG PARAPHERNALIA) to provide an exception for manufacturers delivering needles/syringes through a disease control program.</p>	04/16/2009 H Considered by s/c in work session
HB 272	Ortiz		Relating to disease control programs to reduce the risk of certain communicable diseases.	<p>Adds Subchapter J: Programs to Reduce Risk of Certain Communicable Diseases to Chapter 81 of the Health and Safety Code. Allows local health authorities to establish disease control programs that provide for anonymous exchange of used hypodermic needles/syringes for equal number of new ones; offers education on transmission/prevention of communicable diseases including HIV, Hep B and Hep C; assists participants in obtaining health services/testing/substance abuse/etc; and provides proper medical waste containers and info on safe disposal of syringes. Allows local health authorities to charge a fee for each hypodermic needle/syringe.</p> <p>Requires annual reporting by local health authority to DSHS on effectiveness of program and impact on reducing the spread of communicable diseases.</p> <p>Allows wholesale drug/device distributors to distribute hypodermic needles/syringes to authorized disease control programs.</p> <p>Establishes procedures for storage of needles/syringes.</p> <p>Creates an exception to Section 481.125 of the Health and Safety Code (OFFENSE: POSSESSION OR DELIVERY OF DRUG PARAPHERNALIA) for manufacturers and those</p>	04/16/2009 H Considered by s/c in work session



Medical Device Legislative Tracking Chart

				who use/possess/delivers needles/syringes through a disease control program and presents evidence showing they are an employee/volunteer/participant of disease control program.	
HB 344	Leibowitz		Relating to reimbursement under the state Medicaid program for health care services associated with certain adverse events.	<p>Adds Section 32.0312: Reimbursement Prohibited for Services Associated with Preventable Adverse Events to Chapter 32 (Medical Assistance Program) of the Human Resources Code. Defines "serious disability" and "serious injury".</p> <p>Prohibits DSHS from providing reimbursement under medical assistance program to a health care provider for a health care services provided in association with a preventable adverse event, including services provided as a result of or to correct consequences of a preventable adverse event.</p> <p>Defines a preventable adverse event for medical assistance recipients as: surgery on the wrong body part, surgery on the wrong person, wrong surgical procedure performed, unintended retention of a foreign object in a person after surgery/procedure, death during/immediately after surgery if person is normal/healthy, death/disability caused by the use of a contaminated drug/device/biologic if contamination is the result of a generally detectable contaminant in drugs/devices/biologics regardless of source of contamination, death/disability caused by the use/function of a device other than for what it is intended, death/disability caused by intravascular air embolism, infant discharged to wrong person, death/disability associated with disappearance over four hours, suicide/attempted resulting in disability while receiving care in a health care facility, death/disability caused by medication error including administration of wrong drug/dose/patient/time/rate/preparation, death/disability caused by hemolytic reaction, death/disability caused by labor/delivery in a low-risk pregnancy, death/disability from hypoglycemia, death/disability from failure to treat hyberbilirubinemia in a neonate, stage 3/4 pressure ulcers acquired after admission, death/disability from spinal manipulative therapy, death/disability caused by electric shock, oxygen line mistakes, burns, falls, restraint use, care by persons impersonating a physician/nurse/etc, abduction from health care facility, sexual assault while in a health care facility, physical assault while in a health care facility, and AI with wrong donor sperm/egg.</p> <p>Refusal to reimburse does not itself create civil liability and is not subject to</p>	02-26-09 H <u>Re-referred</u> to Committee on House Public Health



Medical Device Legislative Tracking Chart

				discovery/admissible in civil actions against the provider.	
HB 808	Gallego		Relating to the availability of automated external defibrillators at certain athletic clubs.	Adds Section 779.009: Athletic Clubs; Limitation on Liability; Civil Penalty to the Health and Safety Code. Requires athletic clubs to make automated external defibrillators available at each facility. Must make reasonable effort to have at least one employee trained in proper use of AED present during business hours at facility. Exempts club from civil damages from use/attempted use/failure to use an AED unless they act in a wanton/willful manner or in gross negligence. Civil penalties for noncompliance of up to \$200 for first violation. Subsequent violations up to \$500 each. Allows AG, DA, CA, or City Attorney to sue to collect; funds go to local government.	05-14-09 H Postponed on second reading until 11:30 p.m., Thursday, May 14, 2009.
HB 844	Martinez	SB 26 by Zaffirini	Relating to health benefit plan coverage for certain prosthetic devices, orthotic devices, and related services.	Adds Chapter 1371: Coverage for Certain Prosthetic Devices, Orthotic Devices, and Related Services to Title 8 of the Insurance Code. Defines: enrollee, orthotic device, and prosthetic device. Defines applicability. Requires health benefit plans to provide coverage for orthotic and prosthetic devices and professional services related to the fitting and use of those devices equal to coverage required by federal law for aged and disabled. Coverage is limited to the most appropriate model of device adequately meeting needs of enrollee as determined by enrollee's treating physician/prosthetist/orthotist. Preauthorization allowed.	03-10-09 H Committee action pending House Insurance
HB 989	England		Relating to prior authorization for certain medical devices provided through the medical assistance program.	Adds Section 531.076: Prior Authorization for Certain Implantable Device Prohibited to Chapter 531 of the Government Code. Prohibits HHSC from requiring prior authorization under Medicaid for replacement/revision of implantable infusion pump or implantable electrical nerve stimulator.	02-23-09 H Introduced and referred to committee on House Public Health
HB	Bohac		Relating to the	Requires the Office for the Prevention of Developmental Disabilities, DSHS, and DFPS to	03-02-09 H



Medical Device Legislative Tracking Chart

1426			establishment of a pilot program in certain counties to require health and human services providers to provide screening to prevent fetal alcohol spectrum disorders.	establish a pilot program to: 1. support efforts to identify women at risk for alcohol-exposed pregnancy by creating a network of HHS providers that screen; and 2. provide alcohol education to woman between 18 and 44. Pilot program must be in three urban counties with populations over 1 million with high %age of women documented who engage in alcohol consumption. Requires Counties to: 1. develop an action plan requiring HHS providers to screen for alcohol consumption and provide data to DSHS; 2. adopt rules for minimum screening standards and for reporting data, require each HHS provider to document child's/woman's known substance abuse/alcohol consumption exceeding 4 drinks on one occasion, establish minimum standards for treating women and reporting treatment data to Center for Health Statistics, give highest priority for chemical dependency treatment to women at risk of alcohol-exposed pregnancies, and require sharing of information on prevention to women; 3. train under written protocol: physicians/PAs/nurses/caseworkers/DFPS workers to screen and report data, and counselors to administer interventions; 4. analyze screening data and intervention data; 5. determine number of at risk women; and disseminate information on prevention of fetal alcohol spectrum disorder. Reporting requirement.	Introduced and referred to committee on House Public Health
HB 1577	Isett		Relating to the pricing of certain health care goods and services and to the compensation of certain health insurance agents.	Adds Chapter 254: Patient Access to Pricing Information to the Health and Safety Code. Defines facility as one subject to licensing where a health care practitioner practices. Includes abortion and end stage renal disease facilities but excludes facilities subject to Chapter 324: ambulatory surgical centers, birthing centers, and hospitals. Each facility is required to compile a list of prices charged for each product/service. Must provide copy of list to any requesting patient. Requires facility to provide to patients upon request an itemized billing statement. Requires facilities to refund overpayment by 30 days. Amends Chapter 550 of the Insurance Code to prohibit insurers/affiliates from paying insurance agents compensation for transactions violating disclosure requirements. Amends Chapter 552 of the Insurance Code to state subchapter is not applicable to a patient for which a provider accepts service from Medicaid/Medicare/other federal, state, or local government-sponsored program. Adds Subchapter B: Discounts to Chapter 552 of the Insurance Code to define a health care provider as a licensed individual to practice medicine/pharmacy/chiropractic/nursing/physical/therapy/etc. Subchapter only applies to facilities subject to Chapter 254 (above) or 324 and a health care provider. Allows facilities/health care providers to give discounts to individuals if it is applied to portion of the bill that is the patient's responsibility after facility receives payment from third party payor. Adds Subchapter C: Availability of Pricing Information to require each health care practitioner to compile a list of prices charged for each product/service and provide copy to requesting patients. Requires posting notice of availability of price listing and requires itemized	03-02-09 H Introduced and referred to committee on House Public Health



Medical Device Legislative Tracking Chart

HB 1696	Isett		Relating to the regulation of pharmacy benefit managers and to payment of claims to pharmacies and pharmacists.	<p>billing.</p> <p><u>As Substituted:</u> Adds Chapter 4154: Pharmacy Benefit Managers to Title 13 of the Insurance Code. Defines: covered entity, covered individual, pharmacy benefit management, and pharmacy benefit manager. Subchapter B: Regulation of Pharmacy Benefit Managers Applies to each PBM providing claims processing and/or prescription drug/device services to covered individuals who are residents of TX. Requires PBMs to have a certificate as a third-party administrator. Requires PBMs to notify covered entities of conflicts of interest. PBMS are prohibited from contacting covered entities outside of contract provisions without permission. Allows PBM to substitute lower priced generic and therapeutically equivalent drugs for higher priced prescribed drug or request a therapeutic interchange only as provided. PBM must disclose following information and obtain approval from prescriber before requesting therapeutic interchange: 1. Difference in copayments to covered individuals; 2. Whether drug originally prescribed has a generic equivalent and drug proposed for substitution does not; and 3. Any known clinically significant differences between prescribed drug and proposed substitute including side effects. If the net cost to individual of substituted drug exceeds prescribed drug, substitution can only be made for medical reasons. Prohibits PBMs from substituting equivalent drugs if prescription order prohibits. PBM must notify covered individual if therapeutic interchange is approved. PBMs prohibited from requiring pharmacy network providers to comply with recordkeeping more stringent than required by state or federal law. Requires notice by PBM to pharmacy network providers of termination of covered entity's contracts. Requires PBM to adjust payment to network provider by 3 days after price increase notice from manufacturer/supplier. Amends Section 843.002 of the Insurance Code to define: extrapolation as math process/technique used by HMOs or PBMs in the audit of pharmacy/pharmacist to estimate results for larger group of claims not reviewed. Amends Section 843.339 of the Insurance Code to require PBMs administering claims for HMOs as well as HMOs to pay claims by electronic funds by 14th day. Requires them to pay claims not electronically submitted by 21st day. Amends Section 843.340 of the Insurance Code to prohibit HMOs/PBMs from using extrapolation to complete pharmacist/pharmacy audits. Requires reasonable notice of on-site audits in writing at least 15 days prior. Amends Section 843.344 of the Insurance Code (Applicability of Subchapter to Entities Contracting with Health Maintenance Organization) to include pharmacy benefit managers. Amends Chapter 843 of the Insurance Code to establish a claim payment/complaint procedure through TDI for pharmacists/pharmacies. Requires SOAH to conduct hearings by request of TDI on contested cases. Amends Section 1301.001 of the Insurance Code to include pharmacy and pharmacists in</p>	05-14-09 H Set on the House Calendar
------------	-------	--	---	--	---



Medical Device Legislative Tracking Chart

				the definition of health care provider and to define: extrapolation as math process/technique used by insurers or PBMs in the audit of pharmacy/pharmacist to estimate results for larger group of claims not reviewed. Amends Section 1301.104 of the Insurance Code to require PBMs administering claims for preferred provider insurers to pay claims by electronic funds by 14th day. Requires them to pay claims not electronically submitted by 21st day. Amends Section 1301.105 of the Insurance Code to prohibit insurers/PBMs from using extrapolation to complete pharmacist/pharmacy audits. Requires reasonable notice of on-site audits in writing at least 15 days prior. Amends Section 1301.109 of the Insurance Code (Applicability of Subchapter to Entities Contracting with Insurer) to include pharmacy benefit managers.	
HB 2029	Zerwas	SB 2347 by Hinojosa, SB 2426 by Deuell	Relating to the establishment of a laser and intense pulsed light device registry.	Adds Subchapter M: Laser or Similar Medical Device Registry to Chapter 401 of the Health and Safety Code. Defines laser or similar medical device. Prohibits person from purchasing/possessing laser or similar medical device unless person is a practitioner authorized to use device. Requires practitioners to notify DSHS of purchase/possession of device. DSHS must establish a central registry of devices. Allows DSHS to inspect for compliance. Civil penalty for violating of up to \$1,000 per violation.	04-07-09 H Not heard in committee House Public Health
HB 2183	Zerwas		Relating to the regulation of independent freestanding emergency medical care facilities and urgent care clinics.	Adds Chapter 254: Independent Freestanding Emergency Medical Care and Urgent Care Facilities to the Health and Safety Code. Requires licensing to operate. Lists exceptions for licensure. Requires HHSC to adopt rules for implementation and rules to address specific standards at each facility including: provision of lab and radiological services, distribution/administration of drugs and controlled substances, and contents/release of medical records. Establishes a complaint process as well as a process for denial/suspension/revocation of license. Creates civil and criminal penalties and allows DSHS to collect administrative fees/penalties. Requires insurance companies to cover medically necessary services provided by licensed independent freestanding emergency care facilities.	03-31-09 H Committee action pending House Public Health
HB 2278	Thompson		Relating to health benefit plan coverage under the Texas Employees Group Benefits Act	Amends Chapter 1551 of the Insurance Code to require health benefit plans offering group benefits providing coverage for diabetes to provide coverage for diabetes equipment and supplies.	03-09-09 H Introduced and referred to committee on House Pensions/Investments/Fin



Medical Device Legislative Tracking Chart

			for certain medical supplies.		ancial Services
HB 2279	Thompson		Relating to the provision of and billing for certain diagnostic imaging services.	Adds Chapter 116 to Title 3 of the Occupations Code to state that health care providers violating chapter are subject to disciplinary action and penalties if they do not directly supervise/perform professional component of diagnostic imaging service or fails to disclose in bill an itemized statement to the patient.	05-14-09 H Postponed on second reading until 11:30 p.m., Thursday, May 14, 2009.
HB 2599	Thompson	SB 1461 by Duncan	Relating to the registration of diagnostic imaging equipment, the accreditation of diagnostic imaging facilities, and the regulation of diagnostic imaging providers.	Adds Chapter 113: Diagnostic Imaging to Title 3 of the Occupations Code. Requires HHSC to adopt rules specifying procedures for compliance. Requires registration of diagnostic imaging facilities in order to operate. Requires national accreditation of diagnostic imaging facility before issuance of registration. Requires imaging providers to report: referring provider identity, if referring health care provider is an investor, the number of patients receiving diagnostic imaging services referred by provider, and additional claims data. Information collected is required to be public. Expires September 1, 2010. Establishes civil penalty for violation. Requires DSHS to conduct study on information submitted. Study must compare rates at facilities with providers holding interest, and those without.	04-28-09 H Committee action pending House Public Health
HB 3099	Leibowitz		Relating to the reporting of preventable adverse events and the establishment of a patient safety program in hospitals and	Amends Chapter 241 of the Health and Safety Code to add Subchapter H: Patient Safety Program. Defines serious disability. Requires department to develop a patient safety program for hospitals, grouping them by size for reporting requirements. Requires annual report for hospitals in counties with population greater than 350,000. Requires hospitals to report # of certain occurrences when renewing license. Requires hospitals by 45th day after a preventable adverse event occurs, to conduct a root cause analysis and develop a strategic plan to reduce reoccurrence. All information is confidential. Requires Department to compile an annual summary of reported preventable adverse events and make available to public. Requires hospital to submit a report of best practices/safety measures. Requires DSHS to evaluate patient safety program and make recommendations to Legislature. Adds Subchapter B: Patient Safety	3/18/09 Referred to House Public Health



Medical Device Legislative Tracking Chart

			ambulatory surgical centers; providing an administrative penalty.	Program to Chapter 243 of the Health and Safety Code. Requires Department to create a patient safety program for ambulatory surgical centers. Requires annual reporting for ambulatory surgical centers in counties with population greater than 350,000. Requires ambulatory surgical centers to report # of certain occurrences when renewing license. Requires ambulatory surgical centers by 45th day after a preventable adverse event occurs, to conduct a root cause analysis and develop a strategic plan to reduce recurrence. All information is confidential. Requires Department to compile an annual summary of reported preventable adverse events and make available to public. Requires ambulatory surgical centers to submit a report of best practices/safety measures. Requires DSHS to evaluate patient safety program and make recommendations to Legislature.	
HB 3100	Leibowitz		Relating to billing for certain adverse events that occur during the provision of health care services.	Adds Chapter 183: Prohibited Billing Practices to Title 2 of the Health and Safety Code. Lists preventable adverse events as: 1. unintended retention of a foreign object after surgery; 2. death/disability caused by air embolism; 3. death/disability cause by hemolytic reaction; 4. stage 3/4 pressure ulcers; 5. death/disability caused by electric shock; 6. death/disability caused by burn; 7. death/disability caused by fall; 8. death/disability related to poor glycemic control; 9. death/disability caused by UTI; 10. death/disability caused by vascular catheter infection; 11. death/disability from surgical site infection; and 12. death/disability from pulmonary embolism/deep vein thrombosis. Prohibits providers from presenting bill/invoice which includes costs for a preventable adverse event. Violations subject to disciplinary action.	3/18/09 Referred to House Public Health
HB 3101	Leibowitz		Relating to the deceptive trade practice of charging for certain preventable adverse health care events.	Amends Section 17.46 of the Business & Commerce Code to list as a false, misleading, or deceptive act/practice: act of health care provider resulting in a preventable adverse event. Lists preventable adverse health care events: 1. surgery on wrong body part; 2. surgery on wrong patient; 3. wrong surgical procedure on patient; 4. unintended retention of foreign object; 5. death during/immediately after surgery if patient is classified as normal; 6. death/disability from use of contaminated drug, device, or biologic if the contamination results from generally detectable contaminant; 7. infant discharged to wrong person; 8. death/disability related to patient's disappearance from facility for more than 4 hours; 9. abduction of patient; 10. sexual assault of patient; and 11. death/injury from physical assault of patient.	3/18/09 Referred to House Judiciary and Civil Jurisprudence
HB 3408	Gonzales		Relating to a county's liability for the costs of basic health care services.	As Substituted: Amends Chapter 122 of the Health and Safety Code to allow counties as determined necessary to provide health care services to a person regardless of income. Allows counties to establish standards/application/documentation/verification procedures to determine eligibility.	05-19-09 S Committee action pending Senate Health and



Medical Device Legislative Tracking Chart

					Human Services
HB 3459	Isett		Relating to pricing for health care services and supplies and reimbursement for those services or supplies under certain health benefit plans.	Requires health care providers to compile a list of price charged for each service/supply provided and give to patients who request it. Requires posting of notice in general waiting area of availability of price list. Establishes overpayment and refund procedures. Establishes an offense.	04-28-09 H Committee action pending House Insurance
HB 3749	Coleman		Relating to itemized statements provided by certain health care facilities	<p>As Substituted and amended on House Floor: Requires DSHS to collect information on itemized billing statements of health care facilities including information on unit prices charged to facilities by manufacturers for:</p> <ol style="list-style-type: none"> 1. Medical hardware 2. Devices or implants 3. Prescription specialty drugs or drug protocols 4. MRI, Computed tomography, and positron emission tomography equipment, and 5. Health care services <p>Prohibits health care facilities from including language in their contracts which prohibits disclosure of: 1. Information on unit prices charged to facilities by manufacturers/suppliers/providers of devices, implants, prescription specialty drugs, drug protocols, or medical hardware, or 2. Other pricing information related to the contract. Interim committee is composed of 3 Senators appointed by Lt. Gov. and 3 Representatives appointed by Speaker.</p> <p>Study must include:</p> <ol style="list-style-type: none"> 1. Manner in which billing statement accurately reflects actual unit prices charged to facility (and if discounts/rebates/adjustments are taken into account) 2. Effects of facility billing practices on patient access to health care and on 3rd party payors, including effects of pricing/discounting on the uninsured/underinsured/insurers/governmental payors/3rd party payors 3. Economic consequences of health care facility billing practices on consumers/3rd party 	05-20-09 S Received in the Senate - Referred to Senate Committee on Administration



Medical Device Legislative Tracking Chart

				<p>payors</p> <p>4. Resolution of patient complaints on facility-billed charges and billing practices</p> <p>5. Effects of billing practices related to increases in the amount of the billed unit prices compared to actual unit prices. Report due by December 1, 2010.</p>	
HB 3891	Vaught		Relating to certain health benefit plan coverage for bilateral cochlear implants and related services.	Amends Title 8 of the Insurance Code to require a health benefit plan to provide coverage for minor enrollees for bilateral cochlear implants and services related to fitting and use. Allows preauthorization.	03-23-09 H Introduced and referred to committee on House Insurance
HB 3909	Madden		Relating to the computation of the franchise tax.	Allows SICM Industry Group 735: Medical Equipment, Heavy Construction Equipment, and Equipment rental and leasing to qualify as an entity primarily engaged in wholesale or retail for franchise tax purposes.	04-20-09 H Committee action pending House Ways and Means
HB 4087	Farrar		Relating to the establishment of an ultrasound machine registry.	Adds Chapter 325: Ultrasound Machines to the Health and Safety Code. Restricts possession and use of ultrasound machines to licensed practitioners or facility with at least one practitioner. Requires practitioner/facility to notify department of purchase/possession of ultrasound machine. Requires department establish a central registry of ultrasound machines. Allows for inspections. Establishes a civil penalty for violations.	03-23-09 H Introduced and referred to committee on House Public Health
HB 4572	Zerwas	SB 64 by Zaffirini	Relating to insurance coverage for certain devices that facilitate insulin therapy and enhance	Amends Section 1358.051 of the Insurance Code to define "diabetes equipment" and "diabetes supplies" to include devices that facilitate insulin therapy and enhance glucose control.	03-26-09 H Introduced and referred to committee on House Insurance



Medical Device Legislative Tracking Chart

			glucose control in the treatment of diabetes.		
SB 8	Nelson		Relating to the administration, powers, and duties of the Texas Health Services Authority.	<p>As Substituted: Amends Section 182 of the Health and Safety Code dealing with the Texas Health Services Authority.</p> <p>Adds to the responsibilities of the Texas Health Services Authority the responsibility to make recommendations to improve the quality of health care funded by both public and private payors and to increase accountability and transparency.</p> <p>Defines:</p> <ol style="list-style-type: none"> 1. clinical integration as a network of practitioners implementing an active and ongoing program to evaluate/modify practice patterns to control costs and ensure quality. 2. global payments are compensation paid to a practitioner/facility for providing/arranging a defined set of covered services to participating persons. Compensation is based on predetermined payment. 3. health care facility is a hospital/emergency clinic/outpatient clinic/birthing center/ambulatory surgical center. <p>Additionally defines health care practitioner, and payor.</p> <p>Corporation is additionally established to research/develop/support/promote strategies (including those based on nationally recognized organizations) to improve quality of health care and increase accountability/transparency through voluntary implementation of: evidence-based best practice standards, performance measures, improved payment methodologies, and streamlined administrative processes.</p> <p>Corporation is administratively tied to HHSC and CSSB 8 lists responsibilities of HHSC with regards to the Texas Health Services Corporation.</p> <p>Expands corporation's governing board to 15 including: 5 appointed by Governor, 5 appointed by Governor from a list provided by Speaker, and 5 appointed by Lt. Governor. Includes ex officio/non-voting members: DSHS Commissioner, HHSC Commissioner, TDI Commissioner, ERS ED, TRS ED, and HHSC state Medicaid director. Requires board to meet at least once a quarter and establishes that meetings are open to the public and the board must provide notice. Board is required to hire a medical advisor, physician licensed to practice in Texas.</p>	05-25-09 H Set on the House Calendar



Medical Device Legislative Tracking Chart

				<p>Requires the Board to establish an advisory committee on technology and an advisory committee on evidence-based best practices and quality of care. Allows the board to establish additional advisory committees as necessary. Requires appointees to the advisory committees to be individuals with significant experience and at least one member with practical experience, and who represent both public and private sectors and affected groups.</p> <p>Eliminates from general powers a duties the requirement that the corporation identify standards for streamlining health care administrative functions.</p> <p>Requires corporation to research/develop/support/promote:</p> <ol style="list-style-type: none"> 1. evidence-based best practice standards for practitioners/facilities, 2. strategies to encourage adherence to evidence-based best practices, 3. performance measures to evaluate quality of care, 4. standards for reporting results of performance measures and comparing, 5. recommendations for disseminating results to public, 6. standards for technology to collect information, 7. strategies for using existing resources, 8. strategies to facilitate exchange of health care info and interoperability and standardization, 9. recommendations to encourage clinical integration, 10. alternative payment methodologies for payors, 11. standards for streamlining health care administrative functions across payors, and 12. recommendations for streamlining health care administrative functions such as lab results, diagnostic imaging and prescription histories/patient identification/enrollee status/status of plan contracted practitioners. <p>Requires board to examine existing standards/guidelines/strategies/methodologies created by nationally recognized organizations and those used in federal Medicare program.</p> <p>Adds Section 182.1015: Studies on Payment Methodologies. Requires corporation to conduct or contract for a study to develop payment incentives and increase access to primary care. Must evaluate proposals that:</p> <ol style="list-style-type: none"> 1. reward primary care practitioners for retention, 2. encourage spending appropriate time with each patient, 3. reward for monitoring patients/follow-up care, 4. provide incentives for 24-hour availability to reduces unnecessary ER visits, and 5. improve access to primary care. <p>Corporation must conduct or contract for a study on risk-adjusted episodes of care and must:</p>	
--	--	--	--	---	--



Medical Device Legislative Tracking Chart

				<ol style="list-style-type: none"> 1. evaluate payment methodologies and 2. identify high-cost, frequently performed procedures. <p>Both above studies must:</p> <ol style="list-style-type: none"> 1. examine: <ol style="list-style-type: none"> a. payment methodologies of nationally recognized organizations; b. payment methodologies promoting evidence-based best practices; and c. payment methodologies used by federal Medicare system, and 2. include recommendations on achieving maximum practitioner, facility, and payor participation. <p>Reporting requirement to Legislature on summary of results of studies conducted and recommendations.</p> <p>Repeals Section 182.102 of the Health and Safety Code: Prohibited Acts of the Texas Health Services Authority.</p>	
SB 26	Zaffirini	HB 844 by Martinez	Relating to health benefit plan coverage for certain prosthetic devices, orthotic devices and related services.	<p>Adds Chapter 1371: Coverage for Certain Prosthetic Devices, Orthotic Devices, and Related Services to Title 8 of the Insurance Code.</p> <p>Defines: enrollee, orthotic device, and prosthetic device. Defines applicability. Requires health benefit plans to provide coverage for orthotic and prosthetic devices and professional services related to the fitting and use of those devices equal to coverage required by federal law for aged and disabled. Coverage is limited to the most appropriate model of device adequately meeting needs of enrollee as determined by enrollee's treating physician/prosthetist/orthotist.</p> <p>Preauthorization allowed.</p>	04-15-09 S Committee action pending Senate State Affairs
SB 64	Zaffirini	HB 4572 by Zerwas	Relating to insurance coverage for certain devices that facilitate insulin therapy and enhance glucose	Amends Section 1358.051 of the Insurance Code to define "diabetes equipment" and "diabetes supplies" to include devices that facilitate insulin therapy and enhance glucose control.	05-04-09 H Referred to House Committee on House Insurance



Medical Device Legislative Tracking Chart

			control in the treatment of diabetes.		
SB 188	Deuell	HB142 by McClendon	Relating to disease control programs to reduce the risk of certain communicable diseases.	As Substituted by House: Includes statement of finding that individuals addicted to drugs need to receive education and treatment for addiction. Outreach programs created under act will provide necessary access to health care and ensure safe disposal of syringes/needles. It is intent of legislature that there will be increased access to treatment centers, increased treatment, and increased safety. Adds Subchapter J:OUTREACH PROGRAMS TO REDUCE RISK OF CERTAIN COMMUNICABLE DISEASES to Chapter 81 of the Health and Safety Code. Applies only to counties with populations of 300,000 or more. Allows local health authorities to establish disease control outreach program that: 1. assists participants in obtaining health care/mental health services/substance abuse treatment; 2. offers education on transmission/prevention of communicable diseases; and 3. provides for anonymous exchange of used hypodermic needles/syringes for equal number of new ones. Can charge participants a fee for each needle/syringe used in program of not more than 150% of its actual cost. Annual reporting requirement to DSHS on: 1. effectiveness of outreach program including # served and methods of distribution; 2. program's impact on reducing spread of communicable diseases; and 3. effect on injected drug use in area. Allows licensed wholesale drug distributors or device distributors to distribute hypodermic needles/syringes to these programs. Sets storage requirements. Amends Section 481.125 of the Health and Safety Code (OFFENSE: POSSESSION OR DELIVERY OF DRUG PARAPHERNALIA) to provide a defense to prosecution for manufacturers delivering needles/syringes through a disease control program, or person uses/possesses/delivers needles/syringes and presents evidence that they are an employee/volunteer/participant.	05-23-09 H Set on the House Calendar
SB 296	West		Relating to the disclosure of certain payments or other transfers of value by manufacturers of prescription drugs, medical devices, and	Adds Chapter 174: Reporting Requirements for Manufacturers of Prescription Drugs, Medical Devices, and Medical Supplies to Title 2 of the Health and Safety Code. Chapter applies to manufacturers whose annual gross revenue exceeds \$1 million and that produces, prepares, compounds, converts, or processes a prescription drug, medical device, or medical supply for which payment is available through the medical assistance program under Chapter 32 of the Human Resources Code, or under Title XVIII, XIX, or XXI of the Social Security Act. Gives the AG rulemaking authority to implement. Requires quarterly reporting for manufacturers doing business in Texas disclosing any payment/transfer of value directly/indirectly or through an agent/subsidiary/third party to: a physician, entity which employs/gives tenure to/or is owned by a physician, or an organization	See SB 553



Medical Device Legislative Tracking Chart

			<p>medical supplies; providing a penalty.</p>	<p>involved in health care financing/organization/delivery in which a physician is a voluntary paying member or receives professional certification through. Requires the following information to be provided for each payment/transfer of value: 1. Name of physician, entity associated/employed by, organization involved in, address of the physician's/entity's office, facility with which physician is affiliated, value of the payment, date on which payment/value was provided, description of payment/value, and purpose of payment/value. Exempts from quarterly reporting: 1. Free samples of prescription drugs for distribution to patients, 2. Transfer of anything of value to a physician who is a patient and not acting in professional capacity, 3. A gift/payment/fee/subsidy/economic benefit less than \$25, and 4. Compensation paid to a physician directly employed by and works solely for a manufacturer. Requires annual summary report to AG of: 1. Summary of each submission above made by manufacturer in previous fiscal year, and 2. Includes aggregate amount of all transfers of value less than \$25 for the previous fiscal year. Allows the AG to assess a fee for filing sufficient to cover cost of administering chapter. AG required to report to legislature annually. Imposes a civil penalty for failure to report payment/transfer of value of between \$500 and \$2,500 for each violation not to exceed \$50,000 in one fiscal year. Failure to file quarterly or annual summary is a civil penalty between \$5,000 and \$25,000 not to exceed \$250,000 in one fiscal year. Each failure to report or failure to file constitutes a separate violation. AG may sue to collect. 1st quarterly report is to be submitted December 30, 2009. 1st annual report due by October 15, 2010.</p>	
SB 553	Lucio		<p>Relating to the disclosure of certain economic benefits provided by manufacturers or repackagers of prescription drugs.</p>	<p>As Substituted: Defines: bona fide clinical trial, distributor, gift, health professional, manufacturer, marketer, medical device, prescription drug, repackager, and retailer Subchapter applies only to manufacturer/repackager/retailer exceeding \$30 million in gross revenue and that manufactures/markets/sells/distributes/produces/prepares/compounds/converts/processes a medical device, medical supply, or prescription drug available under the medical assistance program. Annual reporting by March 31 of each year to DSHS of any gift/payment/fee/subsidy/economic benefit to a physician/physician's office/hospital/nursing home/pharmacist/health benefit plan administrator or other health professional in connection with detailing/promotional/marketing activities directly or indirectly.</p>	<p>5-18-09 Placed on Senate Intent Calendar</p>



Medical Device Legislative Tracking Chart

				<p>Report must include for each gift/fee/payment/subsidy/benefit:</p> <ol style="list-style-type: none"> 1. Name and address of recipient 2. Value 3. Date of payment/transfer 4. Categorized description of the form of each benefit including: <ol style="list-style-type: none"> a. Cash/equivalent b. In-kind item/service c. Ownership interest/ROI d. Any other category deemed appropriate by Commissioner 5. Categorized description of the nature of each benefit including: <ol style="list-style-type: none"> a. Consulting fee b. Compensation for service other than consulting c. Honoraria d. Gift e. Entertainment f. Food g. Travel h. Education i. Research j. Charitable contribution k. Royalty/license l. Current/prospective ownership investment interest m. Compensation for serving as faculty/speaker for CME program n. Grant o. Any other category deemed appropriate by Commissioner 6. If payment is related to marketing/education/research specific to a particular drug/device/supply, then the name of the product 7. Any other category of information regarding the payment/transfer the Commissioner determines appropriate. <p>DSHS is to make all reports available on the website by March 31 of each year. Reporting requirements do not apply in areas of disaster declared by Governor during the 30-day period after the order/proclamation is issued. Exemptions from disclosure:</p> <ol style="list-style-type: none"> 1. Gift/fee/payment/subsidy/economic benefit with fair market value less than \$50 	
--	--	--	--	---	--



Medical Device Legislative Tracking Chart

				<ol style="list-style-type: none"> 2. Free samples of prescription drugs intended for distribution to patients 3. Any prescription drug rebate/discount 4. Payment of reasonable compensation/reimbursement of expenses in connection with a bona fide clinical trial 5. Scholarship/support for a medical student/resident/fellow to attend bona fide educational/scientific/policy-making conference of established professional association 6. Grant/support for development/production/presentation of bona fide educational/scientific/policy-making program of established professional association 7. Educational materials directly benefitting patients 8. In-kind items for charity care 9. Transfer/payment of benefit to treat a health condition of a health professional where individual is a patient 10. Dividend/profit distribution from/ownership interest in mutual fund/publicly traded security 11. Loan of a device for a short-term trial period not over 90 days 12. Items/services provided under contractual warranty including replacement of a device <p>Allows HHSC Commissioner to assess an administrative penalty for failure to report. AG can bring action for injunctive relief and impose a civil penalty of up to \$10,000 for failure to file.</p> <p>Each failure to file is a separate violation.</p> <p>Information submitted is considered public record.</p> <p>If federal law providing for the disclosure of gifts to health professionals by manufacturers/repackagers/retailers and HHSC Commissioner determines law is substantial to meet purposes of this bill, DSHS is required to suspend application of state reporting requirements.</p> <p>Requires HHSC to adopt rules/procedures for implementation by March 31, 2011. DSHS must develop reporting form by March 31, 2011.</p> <p>Manufacturers/repackagers/retailers of prescription drugs/medical devices/medical supplies are not required to report until after March 31, 2012.</p> <p>Act is effective January 1, 2011.</p>	
SB	Lucio		Relating to the	Adds Chapter 703: Clinical Laboratory Science Professionals to Title 3 of the Occupations	04-28-09 S



Medical Device Legislative Tracking Chart

775			licensing and regulation of clinical laboratory science professionals.	Code. Purpose of chapter is to ensure better protection of public health by requiring minimum qualifications for clinical lab science professionals and ensure that lab tests are performed competently. Chapter does not apply to individuals licensed to engage in health care services within scope of practice; individuals engaged in lab practices in employ of federal government; individuals in lab science engaged exclusively in research if not used in health maintenance/diagnosis/treatment of disease; students/trainees enrolled in lab science education programs; individuals performing waived/provider-performed microscopy tests; and individuals performing non-waived point-of-care testing. Clinical Laboratory Science Advisory Board established is subject to sunset September 1, 2021. HHSC Commissioner has rule-making authority for qualifications for licensure, renewal of licenses, standards of professional conduct, authorization of certification exams, and criteria for continuing education. Allows establishment of fees to cover costs of administration. DSHS is authorized to examine criminal convictions/guilty pleas/deferred adjudication of applicants for licensure. Requires DSHS to maintain a registry of licensed individuals. Requires DSHS to compile information of consumer interest. Creates the Clinical Laboratory Science Advisory Board of 7 members appointed by Governor: 4 who are licensed clinical lab science professionals (1 who is not a physician lab director and 1 who is a clinical lab scientist); 1 physician; 1 physician who is not a lab director/pathologist; and 1 public member. Members serve 3 year staggered terms. Contains restrictions on appointees. Advisory Board is to meet 2 times annually. Duties are to provide advice and recommendations to DSHS and HHSC on technical matters relevant to chapter. Requires licensure to perform clinical laboratory tests. Defines application process and requirements for license. Establishes categories for licensure: categorical clinical laboratory scientist license, clinical laboratory technician, clinical laboratory specialist in molecular biology, clinical laboratory specialist in cytogenetics, clinical laboratory specialist in histocompatibility, temporary license, and provisional license. Establishes a civil penalty.	Committee action pending Senate Health and Human Services
SB 821	Shapiro		Relating to the regulation of medical radiological technology.	As Engrossed: Amends Section 601.002 of the Occupations Code to define: radiologist and radiological assistant. Amends Section 601.053 of the Occupations Code to require the Board to establish minimum standards for approving curricula/education programs to train radiologist assistants and approve instructors to teach curricula/education programs to train radiologist assistants to provide radiology services under the supervision of a radiologist. Amends Chapter 601 of the Occupations Code to establish certification and requirements for a radiologist assistant: 1. hold general certificate to perform radiologic procedures, 2. complete an advanced academic program with nationally recognized radiologist assistant curriculum, 3. be certified in advanced cardiac life support, and 4. be registered with ARRT and credentialed. Board, with	05-19-09 H Committee action pending House Public Health



Medical Device Legislative Tracking Chart

				the advice and consent of the TMB, has rulemaking authority to determine scope of practice/qualifications. Prohibits radiologist assistants from interpret images/make diagnoses/prescribe medication or therapies.	
SB 1128	Nichols		Relating to an exemption from the sales tax for medical equipment used by physicians in certain areas of the state.	Amends Chapter 151 of the Tax Code to provide an exemption from the state sales tax for tangible personal property sold to/used by a physician in a medically underserved/health professional shortage area and used to diagnose/prevent/alleviate/cure human illness or injury. Exemption does not apply to tangible personal property not used directly to diagnose/prevent/alleviate/cure illness or is rented or leased to a physician for less than one year.	03-13-09 S Introduced and referred to committee on Senate Finance
SB 1193	Wentworth		Relating to the maintenance and service of certain medical devices in health care facilities.	As Substituted: Adds Section 431.0215 to the Health and Safety Code to prohibit a person from calibrating/repairing/performing preventive maintenance on a USFDA class II or III medical device in a medical facility unless person: 1. holds an associate of applied science degree as a biomedical equipment technician or medical imaging specialist, or holds a similar degree; 2. has completed a program of service/maintenance of medical devices by US military; 3. holds an associates degree in electronics field or info management field and has been actively engaged in service/maintenance of medical devices for 2 of preceding 4 years under supervision; or 4. holds evidence of satisfactory completion of training from a medical device manufacturer. Does not apply to devices used only for teaching and research purposes; in-service or software upgrades of a medical device by employee/sales rep; or routine evaluations specified by manufacturer. An Offense is a class C misdemeanor.	05-15-09 H Referred to House Committee on House Public Health
SB 1461	Duncan	HB 2599 by Thompson	Relating to the registration of diagnostic imaging equipment, the accreditation of diagnostic imaging facilities, and the regulation of diagnostic	Adds Chapter 113: Diagnostic Imaging to Title 3 of the Occupations Code. Requires HHSC to adopt rules specifying procedures for compliance. Requires registration of diagnostic imaging facilities in order to operate. Requires national accreditation of diagnostic imaging facility before issuance of registration. Requires imaging providers to report: referring provider identity, if referring health care provider is an investor, the number of patients receiving diagnostic imaging services referred by provider, and additional claims data. Information collected is required to be public. Expires September 1, 2010. Establishes civil penalty for violation. Requires DSHS to conduct study on information submitted. Study must compare rates at facilities with providers holding interest, and those without.	03-17-09 S Introduced and referred to committee on Senate Health and Human Services



Medical Device Legislative Tracking Chart

			imaging providers.		
SB 1603	Shapleigh		Relating to requiring financial disclosure concerning reports prepared by public institutions of higher education for other entities.	Amends Chapter 51 of the Education Code to require higher ed institutions that receive money to conduct research, analysis, survey, or other work to report work and include: statement of receipt of payment, identity of payor, and amount of payment.	05-21-09 H Referred to House Committee on House Higher Education
SB 2347	Hinojosa	SB 2426 by Deuell, HB 2029 by Zerwas	Relating to the establishment of a laser and intense pulsed light device registry.	Adds Subchapter M: Laser or Similar Medical Device Registry to Chapter 401 of the Health and Safety Code. Defines laser or similar medical device. Prohibits person from purchasing/possessing laser or similar medical device unless person is a practitioner authorized to use device. Requires practitioners to notify DSHS of purchase/possession of device. DSHS must establish a central registry of devices. Allows DSHS to inspect for compliance. Civil penalty for violating of up to \$1,000 per violation.	03-31-09 S Introduced and referred to committee on Senate Health and Human Services
SB 2426	Deuell	HB 2029 by Zerwas, SB 2347 by Hinojosa	Relating to the establishment of a laser and intense pulsed light device registry.	Adds Subchapter M: Laser or Similar Medical Device Registry to Chapter 401 of the Health and Safety Code. Defines laser or similar medical device. Prohibits person from purchasing/possessing laser or similar medical device unless person is a practitioner authorized to use device. Requires practitioners to notify DSHS of purchase/possession of device. DSHS must establish a central registry of devices. Allows DSHS to inspect for compliance. Civil penalty for violating of up to \$1,000 per violation.	03-31-09 S Introduced and referred to committee on Senate Health and Human Services