



# Louisiana Board of Pharmacy

3388 Brentwood Drive  
Baton Rouge, Louisiana 70809-1700  
[www.pharmacy.la.gov](http://www.pharmacy.la.gov)



July 10, 2013

Senator John A Alario, Jr, President  
Louisiana Senate  
PO Box 94183  
Baton Rouge, LA 70804-9183

Via Email: [APA.SenatePresident@legis.la.gov](mailto:APA.SenatePresident@legis.la.gov)

## Electronic Mail – Delivery Receipt Requested

Re: Report No. 1 of 3 for Regulatory Project 2013-5 ~ Collaborative Drug Therapy Management

Dear Senator Alario:

The Board has initiated the rulemaking process to amend its existing rules relative to collaborative drug therapy management. It has been suggested the current rules governing the process by which physicians and pharmacists collaborate to manage the drug therapy of their patients are cumbersome and overly restrictive. In cooperation with the Board of Medical Examiners, which will be proposing similar amendments to its existing rules, the Board of Pharmacy proposes to streamline the administrative process for those pharmacists engaged in collaborative drug therapy management. In connection with this regulatory project, you should find the following documents in this packet:

- Notice of Intent
- Proposed Rule
- Family Impact Statement
- Poverty Impact Statement
- Regulatory Flexibility Analysis
- Solicitation of Comments
- Fiscal & Economic Impact Statement

As indicated in the solicitation, we will convene a public hearing on August 27, 2013 to receive public comments and testimony on this proposal. We will summarize those comments and our responses thereto in our next report to you. In the event you have any questions or need additional information, please contact me directly at [mbroussard@pharmacy.la.gov](mailto:mbroussard@pharmacy.la.gov) or 225.925.6481.

For the Board:

*Malcolm Broussard*

Malcolm J Broussard  
Executive Director

cc: Chair, Senate Health & Welfare Committee  
Via Email: [APA.S-H&W@legis.la.gov](mailto:APA.S-H&W@legis.la.gov)  
Speaker, House of Representatives  
Via Email: [APA.HouseSpeaker@legis.la.gov](mailto:APA.HouseSpeaker@legis.la.gov)  
Chair, House Health & Welfare Committee  
Via Email: [APA.H-H&W@legis.la.gov](mailto:APA.H-H&W@legis.la.gov)  
Director, Community Outreach Services, La. Economic Development  
Via Email: [Witty@la.gov](mailto:Witty@la.gov)  
Editor, Louisiana Register  
Via Email: [Catherine.Brindley@la.gov](mailto:Catherine.Brindley@la.gov)  
Reference File

**Pharmacy Program**  
Tel. 225.922.0852  
Fax. 225.925.6499

**CDS Program**  
Tel. 225.925.4770  
Fax. 225.925.4799

**PMP Office**  
Tel. 225.925.4767  
Fax. 225.925.6408

**Executive Office**  
Tel. 225.925.6496  
Fax. 225.922.0316

**Notice of Intent**

**Department of Health and Hospitals  
Board of Pharmacy**

**Collaborative Drug Therapy Management (LAC 46:LIII.523)**

In accordance with the provisions of the Administrative Procedure Act (La. R.S. 49:950 *et seq.*) and the Pharmacy Practice Act (La. R.S. 37:1161 *et seq.*), the Louisiana Board of Pharmacy hereby gives notice of its intent to amend §523 of its rules, for the purpose of simplifying the recordkeeping and reducing the administrative burden for those pharmacists engaging in collaborative drug therapy management activities.

## Louisiana Administrative Code

### Title 46 – Professional and Occupational Standards

#### Part LIII – Pharmacists

#### Chapter 5 – Pharmacists

#### §523. Collaborative Drug Therapy Management

- A. Definitions. As used in this Chapter, the following terms shall have the meaning ascribed to them in this Section:

*Board* – the Louisiana Board of Pharmacy.

*Collaborative Drug Therapy Management* or *Drug Therapy Management* – that practice in which a pharmacist, to the extent authorized by a collaborative drug therapy management agreement, voluntarily agrees with a physician registered with the Louisiana State Board of Medical Examiners, to manage the disease specific drug therapy of one or more patients of such physician, within a predetermined range of medication selected by the physician and set forth in a patient specific written ~~protocol~~ order set. Drug therapy management shall be limited to:

- a. monitoring and modifying a disease specific drug therapy;
- b. collecting and reviewing patient history;
- c. obtaining and reviewing vital signs, including pulse, temperature, blood pressure, and respiration;
- d. ordering, evaluating, and applying the results of laboratory tests directly related to the disease specific drug therapy being managed under ~~written protocol~~ an order set, provided such tests do not require the pharmacist to interpret such testing or formulate a diagnosis;
- ~~e. administration of vaccines to a patient 16 years of age or older by a pharmacist authorized to administer vaccines by the board;~~
- ~~f. providing up to a single seven day supply of a single drug after all refills authorized on the original prescription issued to the patient by the patient's physician have been dispensed; and~~
- g. providing disease or condition specific patient education and counseling.

~~*Collaborative Drug Therapy Management Agreement* – a written document in which a pharmacist and a physician identify the terms and conditions under which they voluntarily agree to participate in collaborative drug therapy management.~~

*Controlled Substance* – any substance defined, enumerated, or included in federal or state statute or regulations, or any substance which may hereafter be designated as a controlled substance by amendment or supplementation of such statute or regulations.

*Disease Specific Drug Therapy* – a specific drug or drugs prescribed by a physician for a specific patient of such physician that is generally accepted within the standard of care for treatment of ~~one of~~ the following diseases or conditions:

- ~~a. treatment and prevention of arterial and venous clot propagation and disease, i.e., anti-coagulant therapy;~~
- ~~b. treatment and prevention of diabetes;~~
- ~~c. adjustment of medication administered by inhalant for treatment of asthma;~~
- ~~d. treatment and prevention of dyslipidemia;~~
- ~~e. smoking cessation therapy;~~
- ~~f. administration of disease specific vaccines to patients 16 years of age or older; and~~
- ~~g. such other drugs, diseases or conditions as may be subsequently recommended by the advisory committee and approved by the board.~~

*Drug* – (a) any substance recognized as a drug in the official compendium, or supplement thereto, designated by the board for use in the diagnosis, cure, mitigation, treatment or prevention of diseases in humans or animals; (b) any substance intended for use in the diagnosis, cure, mitigation, treatment or prevention of diseases in humans or other animals, or (c) any substance other than food intended to affect the structure or any function of the body of humans or other animals.

55 *Drugs of Concern* – a drug that is not a controlled substance but which is nevertheless defined and  
 56 identified in accordance with procedures established by the Louisiana Prescription Monitoring  
 57 Program Act, R.S. 40:1001-1014, as a drug with the potential for abuse.

58 *Pharmacist* – for purposes of this Section, an individual currently licensed by the board who has a  
 59 current unrestricted license to engage in the practice of pharmacy in the this state duly licensed by the  
 60 board, who is approved by the board to engage in collaborative practice for a specific disease or  
 61 condition based on the pharmacist's training and experience.

62 *Physician* – an individual lawfully entitled to engage in the practice of medicine in this state as  
 63 evidenced by a current, unrestricted license duly issued by the Louisiana State Board of Medical  
 64 Examiners.

65 *Prescribe* – a request or order transmitted in writing, orally, electronically or by other means of  
 66 telecommunication for a drug that is issued in good faith, in the usual course of professional practice  
 67 and for a legitimate medical purpose, by a physician for the purpose of correcting a physical, mental or  
 68 bodily ailment of his patient.

69 ~~*Written Protocol Order Set*~~ *Order Set* – a written set of directives or instructions containing each of the  
 70 components specified elsewhere in this Section for collaborative drug therapy management of disease  
 71 specific drug therapy for a specific patient. The ~~written protocol order set~~ shall be signed by the  
 72 physician and represents the physician orders for the collaborative drug therapy management to be  
 73 provided to the patient.

## 74 B. Registration

### 75 1. Eligibility

- 76 a. No pharmacist shall engage in collaborative drug therapy management in this state  
 77 until registered with the board in accordance with this Section. To be eligible for  
 78 registration, a pharmacist shall, as of the date of the application:
- 79 i. possess a current, unrestricted license to practice pharmacy issued by the  
 80 board and not be the subject of a pending investigation or complaint by the  
 81 board or by the pharmacy licensing authority of any other state or  
 82 jurisdiction;
  - 83 ii. be actively engaged in the practice of pharmacy in this state and the  
 84 provision of pharmacist care similar to the activities anticipated in the  
 85 collaborative drug therapy management agreement.
- 86 b. A pharmacist shall be deemed ineligible for registration of collaborative drug  
 87 therapy management who:
- 88 i. does not possess the qualifications prescribed by §523.B.1.a;
  - 89 ii. has voluntarily surrendered or had suspended, revoked, or restricted his  
 90 controlled dangerous substances license, permit, or registration (state or  
 91 federal);
  - 92 iii. has had a pharmacy license suspended, revoked, placed on probation or  
 93 restricted in any manner by the board or by the pharmacy licensing  
 94 authority of any other state or jurisdiction;
  - 95 iv. has had an application for pharmacist licensure rejected or denied; or
  - 96 v. has been, or is currently in the process of being denied, terminated,  
 97 suspended, refused, limited, placed on probation or under other  
 98 disciplinary action with respect to participation in any private, state, or  
 99 federal health insurance program.
- 100 c. The board may, in its discretion, waive the limitations referenced in Subparagraph  
 101 B.1.b of this Section on a case-by-case basis.
- 102 d. The board may deny registration to an otherwise eligible pharmacist for any of the  
 103 causes enumerated in R.S. 37:1241.A, or any other violation of the provisions of  
 104 the Pharmacy Practice Act or the board's rules.
- 105 e. The burden of satisfying the board as to the eligibility of a pharmacist for  
 106 registration to engage in collaborative drug therapy management shall be upon the  
 107 pharmacist. A pharmacist shall not be deemed to possess such qualifications  
 108 unless and until the pharmacist demonstrates and evidences such qualifications in  
 109 the manner prescribed by and to the satisfaction of the board.  
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2. Application and Issuance
- a. Application for registration to engage in collaborative drug therapy management shall be made upon forms supplied by the board. Application forms and instructions may be obtained from the board's website at [www.labbp.com](http://www.labbp.com) or by contacting the board's office.
  - b. An application for registration to engage in collaborative drug therapy management shall include:
    - i. the pharmacist's full name, license number, mailing address of record, and emergency contact information;
    - ii. the nature of the collaborative drug therapy management activities contemplated, i.e., the disease or condition proposed for management;
    - iii. a description of the pharmacist's professional education that qualifies him to engage in collaborative drug therapy management activities described in the agreement application;
    - iv. proof documented in a form satisfactory to the board that the pharmacist possesses the qualifications set forth in this Section;
    - v. ~~a fully executed copy of a collaborative drug therapy management agreement conforming to the requirements of this Section;~~
    - vi. ~~confirmation the pharmacist shall only engage in collaborative drug therapy management to the extent detailed in the agreement and in accordance with the rules of the board; and~~
    - vii. such other information and documentation as the board may require to evidence qualification for registration.
  - c. The board may reject or refuse to consider any application for registration which is not complete in every detail required by the board ~~or may refuse to consider a collaborative drug therapy management agreement which fails to comply with the minimum requirements of this Section.~~ The board may, in its discretion, require a more detailed or complete response to any request for information set forth in the application as a condition to consideration.
  - d. A pharmacist seeking registration to engage in collaborative drug therapy management shall be required to appear before the board or its designee if the board has questions concerning the nature or scope of the pharmacist's application, finds discrepancies in the application, or for other good cause as determined by the board.
  - e. When all the qualifications, requirements, and procedures of this Section are met to the satisfaction of the board, the board shall approve and register a pharmacist to engage in collaborative drug therapy management. Registration of authority to engage in collaborative drug therapy management shall not be effective until the pharmacist receives notification of approval from the board.
  - f. Although a pharmacist shall notify the board each time he intends to engage in collaborative drug therapy management with a physician other than the physician identified in the pharmacist's original application, registration with the board is only required once. The board shall maintain a list of pharmacists who are registered to engage in collaborative drug therapy management.
  - g. Each pharmacist registered to engage in collaborative drug therapy management shall be responsible for updating the board within 10 days in the event of any change in the information recorded in the original application.
3. Expiration of Registration; Renewal
- a. A pharmacist's registration to engage in collaborative drug therapy management with a physician shall terminate and become void, null and without effect upon the earlier of:
    - i. death of either the pharmacist or physician;
    - ii. loss of license of ~~either the pharmacist or physician;~~
    - iii. disciplinary action limiting the ability of ~~either the pharmacist or the physician~~ to enter into collaborative drug therapy management;
    - iv. notification to the board that ~~either the pharmacist or physician~~ has withdrawn from collaborative drug therapy management;

- 169 v. a finding by the board of any of the causes that would render a pharmacist  
 170 ineligible for registration; or  
 171 vi. expiration of a pharmacist's license or registration to engage in  
 172 collaborative drug therapy management for failure to timely renew such  
 173 license or registration.
- 174 b. Registration of authority to engage in collaborative drug therapy management shall  
 175 expire annually on the same day as a pharmacist's license unless renewed by the  
 176 pharmacist by ~~submitting an application to the board upon forms supplied by the~~  
 177 ~~board, together with verification of the accuracy of registration and collaborative~~  
 178 ~~drug therapy management agreement information on file with the board~~  
 179 completing the application form supplied by the board. An application for  
 180 registration renewal shall be made part of and/or accompany a pharmacist's  
 181 renewal application for pharmacist licensure.
- 182 c. The timely submission of an application for renewal of registration shall operate to  
 183 continue the expiring registration in effect pending renewal of registration or other  
 184 final action by the board on such application for renewal.
- 185 C. Advisory Committee. The Collaborative Drug Therapy Management Advisory Committee, constituted  
 186 as provided for in LAC 46:XLV.7417, shall assist the Board of Medical Examiners and the Board of  
 187 Pharmacy on matters relative to collaborative drug therapy management. The President of the Board  
 188 of Pharmacy shall appoint a pharmacist to serve on the committee, and said pharmacist shall serve at  
 189 the pleasure of the Board of Pharmacy.
- 190 D. Standards of Practice
- 191 1. Authority, Responsibility, and Limitations of Collaborative Drug Therapy Management
- 192 a. A pharmacist registered with the board under this Section may engage in  
 193 collaborative drug therapy management with a physician:  
 194 i. ~~to the extent authorized by a collaborative drug therapy management~~  
 195 ~~agreement filed with and approved by the board; and~~  
 196 ii. in accordance with a patient specific, drug specific, disease specific  
 197 ~~written protocol order set,~~ satisfying the requirements of this Section.
- 198 b. A pharmacist engaged in collaborative drug therapy management shall:  
 199 i. retain professional responsibility to his patient for the management of ~~his~~  
 200 their drug therapy;  
 201 ii. establish and maintain a pharmacist-patient relationship with each patient  
 202 subject to ~~the collaborative drug therapy management agreement;~~  
 203 iii. be geographically located to be physically present to provide pharmacist  
 204 care to a patient subject to collaborative drug therapy management;  
 205 iv. provide on a scheduled defined in the written protocol basis no less than  
 206 every three months, a ~~periodic~~ status report on the patient, including but  
 207 not limited to, any problem, complication, or other issues relating to  
 208 patient non-compliance with drug therapy management. This  
 209 requirement may be met by entering the information in the patient's  
 210 medical record; and  
 211 v. be available through direct telecommunication for consultation,  
 212 assistance, and direction.
- 213 c. A pharmacist's registration to engage in collaborative drug therapy management  
 214 with a physician is personal to the pharmacist. A ~~registered~~ pharmacist registered  
 215 to engage in drug therapy management shall not allow another pharmacist not so  
 216 registered or any other individual to exercise the authority conferred by such  
 217 registration. ~~A registered pharmacist shall not engage in collaborative drug~~  
 218 ~~therapy management with a non-physician or with any physician who is not a party~~  
 219 ~~to the pharmacist's collaborative drug therapy management agreement on file with~~  
 220 ~~the board.~~
- 221 d. Collaborative drug therapy management shall only be utilized for ~~those conditions~~  
 222 ~~or diseases identified in, and in the manner specified by, this Section.~~ Additional  
 223 conditions or diseases for which there are generally accepted standards of care for  
 224 disease specific drug therapy may be identified by the advisory committee and  
 225 approved by the board. disease specific drug therapy as defined in this Section.

- 226 e. ~~Only a pharmacist who holds the academic degree of Doctor of Pharmacy, which~~  
 227 ~~degree provided specific training in the area of anti-coagulant drug therapy, shall~~  
 228 ~~engage in collaborative drug therapy management in such particular area of~~  
 229 ~~practice covered by a collaborative drug therapy management agreement. The~~  
 230 ~~board may, in its discretion, grant an exception to this limitation on a case-by-case~~  
 231 ~~basis to a pharmacist who does not possess the academic degree required by this~~  
 232 ~~Section upon the affirmative recommendation and advice of the advisory~~  
 233 ~~committee that the pharmacist possesses the equivalent or other acceptable~~  
 234 ~~advanced training in the area of practice covered by the agreement.~~  
 235 f. The scope of the collaborative drug therapy management shall not include:  
 236 i. any patient of the physician for whom such physician has not prepared a  
 237 patient specific, drug specific, disease or condition specific ~~written~~  
 238 ~~protocol order set based on a face-to-face visit with the patient;~~  
 239 ii. ~~drug therapy management of more than one specific disease or condition.~~  
 240 ~~Administration of a vaccine or smoking cessation therapy are excepted~~  
 241 ~~from this provision.~~  
 242 iii. ~~drug therapy management of any patient by more than one registered~~  
 243 ~~physician and one pharmacist;~~  
 244 iv. ~~any patient under the age of 18 years of age. Administration of a vaccine~~  
 245 ~~or smoking cessation therapy are excepted from this provision.~~  
 246 v. ~~pregnant or nursing mothers;~~  
 247 vi. initiation or discontinuance of drug therapy by a pharmacist, except as  
 248 specified in the ~~written protocol order set;~~  
 249 vii. the management of controlled substances or drugs of concern; or  
 250 viii. substitution of a drug prescribed by a physician without the explicit  
 251 written consent of such physician.

## 2. Informed Consent

- 252 a. A pharmacist shall not engage in collaborative drug therapy management of a  
 253 patient without the patient's written informed consent.  
 254 b. In addition to the requirements provided by law for obtaining a patient's informed  
 255 consent, each patient who is subject to a collaborative drug therapy management  
 256 ~~agreement~~ shall be:  
 257 i. informed of the collaborative nature of drug therapy management for the  
 258 patient's specific medical disease or condition and provided instructions  
 259 and contact information for follow-up visits with the pharmacist and  
 260 physician;  
 261 ii. informed he may decline to participate in a collaborative drug therapy  
 262 management practice and may withdraw at any time without terminating  
 263 the physician-patient or pharmacist-patient relationship; and  
 264 iii. provided written disclosure of any contractual or financial arrangement  
 265 with any other party that may impact one of the party's decision to  
 266 participate in the agreement.  
 267 c. All services provided ~~pursuant to a collaborative drug therapy management~~  
 268 ~~agreement shall be consistent with the agreement and shall be performed in a~~  
 269 ~~setting which insures patient privacy and confidentiality.~~

## 3. ~~Collaborative Drug Therapy Management Agreement~~

- 270 a. ~~A collaborative drug therapy management agreement shall, at a minimum, include:~~  
 271 i. ~~the name, professional license number, address or addresses,~~  
 272 ~~telephone/cell phone number, e-mail address, and emergency contact~~  
 273 ~~information for the pharmacist and physician, and the date of signing and~~  
 274 ~~termination of the agreement;~~  
 275 ii. ~~a description of the manner and circumstances under which the~~  
 276 ~~pharmacist and physician shall engage in collaborative drug therapy~~  
 277 ~~management;~~  
 278 iii. ~~the condition or disease to be managed;~~  
 279 iv. ~~the specific drug or drugs to be utilized for such condition or disease;~~  
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- 282 v. ~~the drug therapy management activities, as defined in this Section, to be~~  
 283 ~~performed by the pharmacist as authorized by the physician;~~  
 284 vi. ~~the procedure to be followed by the parties for drug therapy management~~  
 285 ~~and a plan of accountability defining the respective responsibilities of the~~  
 286 ~~pharmacist and physician;~~  
 287 vii. ~~a plan for reporting and documenting drug therapy management activities~~  
 288 ~~in the pharmacy and medical records and schedule by which such are to~~  
 289 ~~take place. A pharmacist shall submit a report to the collaborating~~  
 290 ~~physician at least every 30 days, or more frequently if warranted by~~  
 291 ~~clinical conditions, regarding the status of a patient's collaborative drug~~  
 292 ~~therapy management, with such report made a part of the pharmacy~~  
 293 ~~record for such patient;~~  
 294 viii. ~~a plan for record keeping, record sharing, and record storage. The~~  
 295 ~~agreement shall acknowledge all collaborative drug therapy management~~  
 296 ~~records shall be treated as and governed by the laws applicable to~~  
 297 ~~physician medical records;~~  
 298 ix. ~~acknowledgement each patient subject to the agreement shall be notified~~  
 299 ~~that a collaborative drug therapy management agreement exists, describes~~  
 300 ~~the procedures for obtaining informed consent of such patient, and the~~  
 301 ~~plan to address patient needs when both the pharmacist and physician are~~  
 302 ~~absent from the practice setting; and~~  
 303 x. ~~the procedure and schedule for reviewing and assessing the quality of~~  
 304 ~~care provided to each patient subject to collaborative drug therapy~~  
 305 ~~management under written protocol.~~  
 306 b. ~~In the event the physician authorizes the pharmacist to order, evaluate, and apply~~  
 307 ~~the results of a laboratory test or tests directly related to disease specific drug~~  
 308 ~~therapy being managed under written protocol, the agreement shall identify the~~  
 309 ~~specific test or tests and describe the plan for securing such testing.~~  
 310 c. ~~The agreement shall affirm that:~~  
 311 i. ~~collaborative drug therapy management shall be in conformity with~~  
 312 ~~generally accepted standards of care for treatment of a patient's specific~~  
 313 ~~disease or condition;~~  
 314 ii. ~~all services provided pursuant to a collaborative drug therapy~~  
 315 ~~management shall be consistent with the agreement and performed in a~~  
 316 ~~setting that insures patient privacy and confidentiality; and~~  
 317 iii. ~~a copy of the agreement shall be maintained on-site by the respective~~  
 318 ~~parties.~~  
 319 d. ~~The agreement may include the identity of one back up pharmacist possessing the~~  
 320 ~~qualifications for collaborative drug therapy management required by this Section,~~  
 321 ~~who shall serve in the absence of the registered pharmacist to the agreement. The~~  
 322 ~~identifying information specified in this Section shall be provided for such~~  
 323 ~~pharmacist, along with an acknowledgement of responsibility to adhere to the~~  
 324 ~~same obligations and commitments imposed on the registered pharmacist to the~~  
 325 ~~agreement, as evidenced by a dated signature.~~  
 326 e. ~~An agreement is valid for a period of time not to exceed one year. A collaborating~~  
 327 ~~pharmacist shall insure that a collaborative drug therapy management agreement is~~  
 328 ~~annually reviewed, updated as appropriate, and signed by the pharmacist and~~  
 329 ~~physician.~~  
 330 f. ~~Each registered pharmacist is responsible for updating the board within 10 days in~~  
 331 ~~the event any of the information required and submitted in accordance with this~~  
 332 ~~Section changes after the board has approved the agreement.~~  
 333 4. ~~Written Protocols Order Sets~~  
 334 a. ~~A separate protocol order set shall be written for each patient to be managed by~~  
 335 ~~collaborative drug therapy management. A copy of each written protocol order set~~  
 336 ~~shall be:~~  
 337 i. ~~provided to the collaborating physician and pharmacist; and~~  
 338 ii. ~~made part of the patient's pharmacy record.; and~~

339 ~~iv. appended by the pharmacist to the collaborative drug therapy~~  
 340 ~~management agreement with the physician and maintained in a separate~~  
 341 ~~file at the pharmacist's practice site listed on the pharmacist's registration~~  
 342 ~~on file with the board.~~

- 343 b. A physician shall develop a patient specific ~~written protocol order set~~ for a  
 344 particular patient or utilize a standard written protocol ~~order set~~ , incorporating  
 345 what patient specific deviations, if any, the physician may deem necessary or  
 346 appropriate for such patient. In either event, ~~an written protocol order set~~ for  
 347 disease specific drug therapy shall adhere to generally accepted standards of care  
 348 and shall identify, at a minimum:
- 349 i. the pharmacist, the physician, and telephone number and other contact  
 350 information for each;
  - 351 ii. the patient's name, address, gender, date of birth, and telephone number;
  - 352 iii. the disease or condition to be managed;
  - 353 iv. the disease specific drug or drugs to be utilized;
  - 354 v. the type and extent of drug therapy management the physician authorizes  
 355 the pharmacist to perform;
  - 356 vi. the specific responsibilities of the pharmacist and physician;
  - 357 vii. the procedures, criteria, or plan the pharmacist is required to follow in  
 358 connection with drug therapy management;
  - 359 viii. the specific laboratory test or tests, if any, directly related to drug therapy  
 360 management the physician authorizes the pharmacist to order and  
 361 evaluate;
  - 362 ix. the reporting and documentation requirements of the pharmacist and  
 363 physician respecting the patient and schedule by which such are to take  
 364 place;
  - 365 x. the conditions and events upon which the pharmacist and physician are  
 366 required to notify one another; and
  - 367 xi. procedures to accommodate immediate consultation by telephone or  
 368 direct telecommunication with, between, or among the pharmacist,  
 369 physician, and the patient.
- 370 c. Each ~~written protocol order set~~ utilized for collaborative drug therapy management  
 371 of a patient shall be reviewed annually by the collaborating ~~pharmacist physician~~,  
 372 or more frequently as such ~~pharmacist physician~~ deems necessary, to address  
 373 patient needs and to insure compliance with the requirements of this Section. A  
 374 ~~collaborating pharmacist's~~ The physician's signature and date of review shall be  
 375 noted on the ~~written protocol order set~~ and maintained by the pharmacist in  
 376 accordance with this Section.

#### 377 ~~5. Administration of Vaccines~~

- 378 a. ~~A collaborative drug therapy management agreement which includes the~~  
 379 ~~administration by a pharmacist of a patient specific order for administration of a~~  
 380 ~~disease specific vaccine shall include documentation of the pharmacist's authority~~  
 381 ~~to administer such medications, pursuant to §521 of the board's rules.~~
- 382 b. ~~In addition to the requirements of this Section, the following information shall be~~  
 383 ~~included in any written protocol for any patient receiving a vaccination from a~~  
 384 ~~collaborating pharmacist:~~
- 385 i. ~~the identity of the drug, dose, and route of administration;~~
  - 386 ii. ~~the date of the original order and the date of any authorized subsequent~~  
 387 ~~dose or administration;~~
  - 388 iii. ~~a statement the patient or patient's tutor, curator, or legal guardian~~  
 389 ~~shall be provided the manufacturer's vaccine information statement with~~  
 390 ~~each dose;~~
  - 391 iv. ~~confirmation written policies and procedures for disposal of used or~~  
 392 ~~contaminated supplies shall be utilized;~~
  - 393 v. ~~a requirement for the pharmacist to immediately report any adverse event~~  
 394 ~~to the collaborating physician and such governmental entities as may be~~

- 395 directed or required by the Louisiana Department of Health and  
 396 Hospitals; and
- 397 vi. ~~confirmation the physician shall be promptly available for consultation~~  
 398 ~~regarding contraindications and adverse reactions in said physician's~~  
 399 ~~patient.~~
- 400 c. ~~This Section shall not prevent or restrict the Louisiana Department of Health and~~  
 401 ~~Hospitals, Office of Public Health, or any other governmental entity of this state~~  
 402 ~~from administering vaccines under the authority of other laws of this state.~~
- 403 6. ~~Additional Refills. Whether or not and the extent to which a collaborating physician may~~  
 404 ~~authorize a collaborating pharmacist to dispense up to a single seven day supply of a single~~  
 405 ~~drug for a single patient utilized for disease specific drug therapy after all refills authorized~~  
 406 ~~for such physician's patient have been dispensed, shall be specifically included in the~~  
 407 ~~collaborative drug therapy management agreement with such pharmacist, as well as the~~  
 408 ~~written protocol applicable to a specific patient.~~
- 409 7. Reporting Obligations and Responsibilities
- 410 a. A pharmacist engaged in collaborative drug therapy management shall ~~notify the~~  
 411 ~~board, in writing, within 10 days of the occurrence or discovery of:~~ report  
 412 annually, as a condition to the renewal of his registration, whether or not and the  
 413 extent to which the pharmacist is engaged in collaborative drug therapy  
 414 management and such other information as the board may request; and
- 415 i. ~~the death of a patient which was, in the pharmacist's opinion, directly~~  
 416 ~~related to drug therapy management;~~
- 417 ii. ~~complications or errors which are, in the pharmacist's opinion, directly~~  
 418 ~~related to drug therapy management;~~
- 419 iii. ~~a pharmacist's termination of a collaborative drug therapy management~~  
 420 ~~agreement with a physician and applicable reasons;~~
- 421 iv. ~~a physician's termination of a collaborative drug therapy management~~  
 422 ~~agreement with a pharmacist and applicable reasons;~~
- 423 v. ~~a patient's election to withdraw from participation in collaborative drug~~  
 424 ~~therapy management and applicable reasons;~~
- 425 vi. ~~his or a physician's failure or refusal to abide by the terms, conditions, or~~  
 426 ~~restrictions of a collaborative drug therapy management agreement or~~  
 427 ~~written protocol and applicable reasons;~~
- 428 vii. ~~the pharmacist's retirement or withdrawal from active practice in this~~  
 429 ~~state or relocation to another state to engage in pharmacy practice; or~~
- 430 viii. ~~the revocation, suspension, or other restriction imposed on a physician's~~  
 431 ~~license which would prohibit the physician from entering into a~~  
 432 ~~collaborative drug therapy management agreement.~~
- 433 b. A pharmacist engaged in collaborative drug therapy management shall comply  
 434 with reasonable requests by the board for personal appearances or information  
 435 relative to the functions, activities, and performance of a pharmacist or physician  
 436 engaged in collaborative drug therapy management.
- 437 8. Records
- 438 a. The following information shall be included in the pharmacy's record of a patient  
 439 subject to collaborative drug therapy management:
- 440 i. the prescription or order implementing collaborative drug therapy  
 441 management;
- 442 ii. the ~~written protocol~~ order set applicable to the patient evidencing  
 443 documentation of the physician's annual review;
- 444 iii. documentation of all activities performed by the pharmacist;
- 445 iv. consultations and status reports by and between the pharmacist and  
 446 physician; and
- 447 v. documentation of the patient's informed consent to collaborative drug  
 448 therapy management.
- 449 b. A pharmacist registered to engage in collaborative drug therapy management shall  
 450 maintain and produce, upon inspection conducted by or at the request of a  
 451 representative of the board, a copy of any ~~or all collaborative drug therapy~~

452 ~~management agreements, amendments thereto, applicable written protocols or~~  
453 ~~sets~~ and such other records or documentation as may be requested by the board to  
454 assess a pharmacist's compliance with requirements of this Section, the Pharmacy  
455 Practice Act, or other applicable board rules.

456 E. Sanctions

- 457 1. Action against Registration. For noncompliance with any of the provisions of this Section,  
458 the board may, in addition to or in lieu of administrative proceedings against a pharmacist's  
459 license, suspend or revoke a pharmacist's registration to engage in collaborative drug therapy  
460 management, or may impose such terms, conditions, or restrictions thereon as the board may  
461 deem necessary or appropriate.
- 462 2. Action against Pharmacist License. Any violation or failure to comply with the provisions of  
463 this Section shall be deemed a violation of R.S. 37:1241.A.1, as well as a violation of any  
464 other applicable provisions of R.S. 37:1241.A, providing cause for the board to take any of  
465 the actions permitted in R.S. 37:1241.A against the pharmacist's license.
- 466 3. Unauthorized Practice. Nothing in this Section shall be construed as authorizing a pharmacist  
467 to issue prescriptions, exercise independent medical judgment, render diagnoses, provide  
468 treatment, assume independent responsibility for patient care, or otherwise engage in the  
469 practice of medicine as defined in the Louisiana Medical Practice Act. Any person who  
470 engages in such activities, in the absence of medical licensure issued by the Louisiana State  
471 Board of Medical Examiners, shall be engaged in the unauthorized practice of medicine and  
472 subject to the penalties prescribed by the Louisiana Medical Practice Act.

473  
474 AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1164(37)(b)(i).

475 HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 33:1125  
476 (June 2007), amended LR

477

**FAMILY IMPACT STATEMENT  
FOR ADMINISTRATIVE RULES**

In accordance with Section 953 of Title 49 of the Louisiana Revised Statutes, there is hereby submitted a family impact statement on the rule proposed for adoption, repeal, or amendment. The following statements will be published in the Louisiana Register with the proposed agency rule.

I. The effect on the stability of the family.

**We can discern no effect on the stability of the family.**

II. The effect on the authority and rights of parents regarding the education and supervision of their children.

**We can discern no effect on the authority and rights of parents regarding the education and supervision of their children.**

III. The effect on the functioning of the family.

**We can discern no effect on the functioning of the family.**

IV. The effect on family earnings and family budget.

**We can discern no effect on family earnings or family budget.**

V. The effect on the behavior and personal responsibility of children.

**We can discern no effect on the behavior and personal responsibility of children.**

VI. The ability of the family or a local government to perform the function as contained in the proposed rule.

**We can discern no effect on the ability of the family or a local government to perform the activity as contained in the proposed rule.**

**POVERTY IMPACT STATEMENT  
FOR ADMINISTRATIVE RULES**

In accordance with Section 973 of Title 49 of the Louisiana Revised Statutes, there is hereby submitted a poverty impact statement on the rule proposed for adoption, repeal, or amendment.

I. The effect on household income, assets, and financial security.

**We anticipate no effect from the proposed rule on household income, assets, and financial security.**

II. The effect on early childhood development and preschool through postsecondary education development.

**We anticipate no impact from the proposed rule on early childhood development or preschool through postsecondary education development.**

III. The effect on employment and workforce development.

**We anticipate no impact from the proposed rule on employment and workforce development.**

IV. The effect on taxes and tax credits.

**We anticipate no impact from the proposed rule on taxes or tax credits.**

V. The effect on child and dependent care, housing, health care, nutrition, transportation, and utilities assistance.

**We anticipate no impact from the proposed rule on child and dependent care, housing, health care, nutrition, transportation, or utilities assistance.**

**REGULATORY FLEXIBILITY ANALYSIS  
FOR ADMINISTRATIVE RULES**

In accordance with Section 965 of Title 49 of the Louisiana Revised Statutes, there is hereby submitted a regulatory flexibility analysis on the rule proposed for adoption, repeal, or amendment. This will certify the agency has considered, without limitation, each of the following methods of reducing the impact of the proposed rule on small businesses:

I. The establishment of less stringent compliance or reporting requirements for small businesses.

The proposed rule change would not change any reporting requirements for small businesses.

II. The establishment of less stringent schedules or deadlines for compliance or reporting requirements for small businesses.

There are no changes in the deadlines for compliance or reporting requirements for small businesses.

III. The consolidation or simplification of compliance or reporting requirements for small businesses.

The proposed rule simplifies the recordkeeping requirement, but there are no changes in the reporting requirements for small businesses.

IV. The establishment of performance standards for small businesses to replace design or operational standards required in the proposed rule.

There are no design or operational standards in the proposed rule.

V. The exemption of small businesses from all or any part of the requirements contained in the proposed rule.

There are no exemptions for small businesses in the proposed rule.

Interested persons may submit written comments to Malcolm J Broussard, Executive Director, Louisiana Board of Pharmacy, 3388 Brentwood Drive, Baton Rouge, Louisiana 70809-1700. He is responsible for responding to inquiries regarding this proposed rule. A public hearing on this proposed rule is scheduled for Tuesday, August 27, 2013 at 9:00 a.m. in the Board office. At that time, all interested persons will be afforded an opportunity to submit data, views, or arguments, either orally or in writing. The deadline for the receipt of all comments is 12:00 noon that same day.

Malcolm J Broussard  
Executive Director  
Louisiana Board of Pharmacy

**FISCAL AND ECONOMIC IMPACT STATEMENT  
FOR ADMINISTRATIVE RULES**

In accordance with Section 953 of Title 49 of the Louisiana Revised Statutes, there is hereby submitted a fiscal and economic impact statement on the rule proposed for adoption, repeal or amendment.

**I. ESTIMATED IMPLEMENTATION COSTS (SAVINGS) TO STATE OR LOCAL GOVERNMENTAL UNITS  
(Summary)**

It is estimated that implementation of the proposed rule will cost the agency \$1,000 in FY 13-14 for printing costs of the Notice of Intent and Final Rule.

**II. ESTIMATED EFFECT ON REVENUE COLLECTIONS OF STATE OR LOCAL GOVERNMENTAL UNITS  
(Summary)**

No impact on state or local governmental revenue collections is anticipated as a result of the proposed rule change.

**III. ESTIMATED COSTS AND/OR ECONOMIC BENEFITS TO DIRECTLY AFFECTED PERSONS OR NON-  
GOVERNMENTAL GROUPS (Summary)**

The proposed rule change may result in a reduction of the administrative burden of pharmacists engaged in collaborative drug therapy management activities, through a reduction of documentation requirements.

**IV. ESTIMATED EFFECT ON COMPETITION AND EMPLOYMENT (Summary)**

We do not forecast any effect on competition or employment from the proposed rule.

FAMILY IMPACT STATEMENT  
FOR ADMINISTRATIVE RULES

Person Preparing

Statement: **Malcolm J. Broussard**  
**Executive Director**

Dept.: **Health and Hospitals**

Office: **Board of Pharmacy**

Telephone: **(225) 925-6481**

Title: **Collaborative Drug Therapy  
Management**

Return Address: **3388 Brentwood Drive**  
**Baton Rouge, LA 70809-1700**

Date Rule  
Takes Effect: **Oct. 20, 2013 (est.)**

In accordance with Section 953 of Title 49 of the Louisiana Revised Statutes, there is hereby submitted a family impact statement on the rule proposed for adoption, repeal, or amendment. The following statements will be published in the Louisiana Register with the proposed agency rule.

I. The effect on the stability of the family.

**We can discern no effect on the stability of the family.**

II. The effect on the authority and rights of parents regarding the education and supervision of their children.

**We can discern no effect on the authority and rights of parents regarding the education and supervision of their children.**

III. The effect on the functioning of the family.

**We can discern no effect on the functioning of the family.**

IV. The effect on family earnings and family budget.

**We can discern no effect on family earnings or family budget.**

V. The effect on the behavior and personal responsibility of children.

**We can discern no effect on the behavior and personal responsibility of children.**

VI. The ability of the family or a local government to perform the function as contained in the proposed rule.

**We can discern no effect on the ability of the family or a local government to perform the activity as contained in the proposed rule.**

  
\_\_\_\_\_  
Signature of Agency Head or Designee

**Malcolm J Broussard, Executive Director**  
Typed Name and Title of Agency Head or Designee

**June 20, 2013**  
\_\_\_\_\_  
Date of Signature

POVERTY IMPACT STATEMENT  
FOR ADMINISTRATIVE RULES

Person Preparing

Statement: **Malcolm J. Broussard**  
**Executive Director**

Dept.: **Health and Hospitals**

Office: **Board of Pharmacy**

Telephone: **(225) 925-6481**

Title: **Collaborative Drug Therapy  
Management**

Return Address: **3388 Brentwood Drive**  
**Baton Rouge, LA 70809-1700**

Date Rule  
Takes Effect: **Oct. 20, 2013 (est.)**

In accordance with Section 973 of Title 49 of the Louisiana Revised Statutes, there is hereby submitted a poverty impact statement on the rule proposed for adoption, repeal, or amendment. The following statements will be published in the Louisiana Register with the proposed agency rule.

I. The effect on household income, assets, and financial security.

**We anticipate no effect from the proposed rule on household income, assets, and financial security.**

II. The effect on early childhood development and preschool through postsecondary education development.

**We anticipate no impact from the proposed rule on early childhood development or preschool through postsecondary education development.**

III. The effect on employment and workforce development.

**We anticipate no impact from the proposed rule on employment and workforce development.**

IV. The effect on taxes and tax credits.

**We anticipate no impact from the proposed rule on taxes or tax credits.**

V. The effect on child and dependent care, housing, health care, nutrition, transportation, and utilities assistance.

**We anticipate no impact from the proposed rule on child and dependent care, housing, health care, nutrition, transportation, or utilities assistance.**



\_\_\_\_\_  
Signature of Agency Head or Designee

**Malcolm J Broussard, Executive Director**  
Typed Name and Title of Agency Head or Designee

**June 20, 2013**  
\_\_\_\_\_  
Date of Signature

REGULATORY FLEXIBILITY ANALYSIS  
FOR ADMINISTRATIVE RULES

Person Preparing

Statement: **Malcolm J. Broussard**  
**Executive Director**

Dept.: **Health and Hospitals**

Office: **Board of Pharmacy**

Telephone: **(225) 925-6481**

Title: **Collaborative Drug Therapy  
Management**

Return Address: **3388 Brentwood Drive**  
**Baton Rouge, LA 70809-1700**

Date Rule  
Takes Effect: **Oct. 20, 2013 (est.)**

In accordance with Section 965 of Title 49 of the Louisiana Revised Statutes, there is hereby submitted a regulatory flexibility analysis on the rule proposed for adoption, repeal, or amendment. This will certify the agency has considered, without limitation, each of the following methods of reducing the impact of the proposed rule on small businesses:

I. The establishment of less stringent compliance or reporting requirements for small businesses.

The proposed rule change would not change any reporting requirements for small businesses.

II. The establishment of less stringent schedules or deadlines for compliance or reporting requirements for small businesses.

There are no changes in the deadlines for compliance or reporting requirements for small businesses.

III. The consolidation or simplification of compliance or reporting requirements for small businesses.

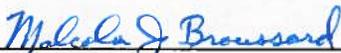
The proposed rule simplifies the recordkeeping requirements, but there are no changes in the reporting requirements for small businesses.

IV. The establishment of performance standards for small businesses to replace design or operational standards required in the proposed rule.

There are no design or operational standards in the proposed rule.

V. The exemption of small businesses from all or any part of the requirements contained in the proposed rule.

There are no exemptions for small businesses in the proposed rule.

  
\_\_\_\_\_  
Signature of Agency Head or Designee

**Malcolm J Broussard, Executive Director**  
Typed Name and Title of Agency Head or Designee

**June 20, 2013**  
\_\_\_\_\_  
Date of Signature

FISCAL AND ECONOMIC IMPACT STATEMENT  
FOR ADMINISTRATIVE RULES

Person Preparing Statement: **Malcolm J. Broussard**  
Executive Director  
Phone: (225) 925-6481  
Return Address: 3388 Brentwood Drive  
Baton Rouge, LA 70809-1700

Dept.: **Health and Hospitals**  
Office: **Board of Pharmacy**  
Title: **Collaborative Drug Therapy Management**  
Date Rule Takes Effect: **Oct. 20, 2013 (est.)**

SUMMARY  
(Use complete sentences)

In accordance with Section 953 of Title 49 of the Louisiana Revised Statutes, there is hereby submitted a fiscal and economic impact statement on the rule proposed for adoption, repeal or amendment. THE FOLLOWING STATEMENTS SUMMARIZE ATTACHED WORKSHEETS, I THROUGH IV AND WILL BE PUBLISHED IN THE LOUISIANA REGISTER WITH THE PROPOSED AGENCY RULE.

I. ESTIMATED IMPLEMENTATION COSTS (SAVINGS) TO STATE OR LOCAL GOVERNMENTAL UNITS  
(Summary)

It is estimated that implementation of the proposed rule will cost the agency \$1,000 in FY 13-14 for printing costs of the Notice of Intent and Final Rule.

II. ESTIMATED EFFECT ON REVENUE COLLECTIONS OF STATE OR LOCAL GOVERNMENTAL UNITS  
(Summary)

No impact on state or local government revenue collections is anticipated as a result of the proposed rule change.

III. ESTIMATED COSTS AND/OR ECONOMIC BENEFITS TO DIRECTLY AFFECTED PERSONS OR NON-GOVERNMENTAL GROUPS (Summary)

The proposed rule change may result in a reduction of the administrative burden of pharmacists engaged in collaborative drug therapy management activities, through a reduction of documentation requirements.

IV. ESTIMATED EFFECT ON COMPETITION AND EMPLOYMENT (Summary)

The proposed rule change will not have any effect on competition or employment.

Malcolm J. Broussard  
Signature of Agency Head or Designee

Malcolm J Broussard, Executive Director  
Typed Name and Title of Agency Head or Designee

June 20, 2013  
Date of Signature

Even Brasseaux, Staff Director  
Legislative Fiscal Officer or Designee

7/9/13  
Date of Signature

**FISCAL AND ECONOMIC IMPACT STATEMENT  
FOR ADMINISTRATIVE RULES**

The following information is required in order to assist the Legislative Fiscal Office in its review of the fiscal and economic impact statement and to assist the appropriate legislative oversight subcommittee in its deliberation on the proposed rule.

- A. Provide a brief summary of the content of the rule (if proposed for adoption, or repeal) or a brief summary of the change in the rule (if proposed for amendment). Attach a copy of the notice of intent and a copy of the rule proposed for initial adoption or repeal (or, in the case of a rule change, copies of both the current and proposed rules with amended portions indicated).

The Board seeks to amend its rule relative to collaborative drug therapy management (CDTM), for the purpose of reducing the administrative burden on pharmacists collaborating with physicians in managing the drug therapy of their patients. In particular, the current requirement for a CDTM agreement is proposed for repeal, and further, certain restrictions in the types of diseases eligible for CDTM are also proposed for repeal. A copy of the Notice of Intent is appended.

- B. Summarize the circumstances that require this action. If the Action is required by federal regulation, attach a copy of the applicable regulation.

The current rule was promulgated by the Board of Pharmacy in 2007; of note, a corresponding rule was jointly promulgated by the Board of Medical Examiners at the same time. Since the promulgation of those rules, less than five CDTM agreements have been approved. Interested practitioners have identified the significant administrative burden as the cause for the low utilization of the CDTM privilege. Both boards have agreed to reduce the administrative burden by jointly promulgating these rule amendments.

- C. Compliance with Act 11 of the 1986 First Extraordinary Session:

- (1) Will the proposed rule change result in any increase in the expenditure of funds? If so, specify amount and source of funding.

We anticipate an increased expenditure for the printing of the proposed and final rules.

- (2) If the answer to (1) above is yes, has the Legislature specifically appropriated the funds necessary for the associated expenditure increase?

(a) \_\_\_\_ Yes. If yes, attach documentation.

(b) \_\_\_\_ No. If no, provide justification as to why this rule change should be published at this time.

The Board operates totally on self-generated funds; we do not receive any appropriations from the legislature.

- D. Compliance with Act 820 of the 2008 Regular Session

- (1) An identification and estimate of the number of small businesses subject to the proposed rule.

Given the criteria in the statutory definition of 'small businesses,' we are unable to specifically identify small businesses because the Board does not collect information from pharmacies concerning the number of employees or any information on sales, net worth, or other financial data.

- (2) The projected reporting, record keeping, and other administrative costs required for compliance with the proposed rule, including the type of professional skills necessary for preparation of the report or record.

The proposed rule change would reduce the recordkeeping requirements and administrative costs associated with CDTM activities.

- (3) A statement of the probable effect on impacted small businesses.

We estimate a potentially positive effect on small businesses.

- (4) A description of any less intrusive or less costly alternative methods of achieving the purpose of the proposed rule.

We can discern no alternative methods of achieving the same purpose of the proposed rule.

FISCAL AND ECONOMIC IMPACT STATEMENT  
WORKSHEET

**I. A. COSTS OR SAVINGS TO STATE AGENCIES RESULTING FROM THE ACTION PROPOSED**

1. What is the anticipated increase (decrease) in costs to implement the proposed action?

<u>COSTS</u>	<u>FY 13-14</u>	<u>FY 14-15</u>	<u>FY 15-16</u>
PERSONAL SERVICES	\$ 0	\$ 0	\$ 0
OPERATING EXPENSES	\$ 1,000	\$ 0	\$ 0
PROFESSIONAL SERVICES	\$ 0	\$ 0	\$ 0
OTHER CHARGES	\$ 0	\$ 0	\$ 0
EQUIPMENT	\$ 0	\$ 0	\$ 0
MAJOR REPAIR & CONSTR.	\$ 0	\$ 0	\$ 0
<b>TOTAL</b>	<b>\$ 1,000</b>	<b>\$ 0</b>	<b>\$ 0</b>
POSITIONS (#)	0	0	0

2. Provide a narrative explanation of the costs or savings shown in "A.1", including the increase or reduction in workload or additional paperwork (number of new forms, additional documentation, etc.) anticipated as a result of the implementation of the proposed action. Describe all data, assumptions, and methods used in calculating these costs.

We anticipate the printing costs for the implementation of the proposed rule to approximate \$1,000 (\$500 for the Notice of Intent and the same amount for the Final Rule).

3. Sources of funding for implementing the proposed rule or rule change.

<u>SOURCE</u>	<u>FY 13-14</u>	<u>FY 14-15</u>	<u>FY 15-16</u>
STATE GENERAL FUND	\$ 0	\$ 0	\$ 0
AGENCY SELF-GENERATED	\$ 1,000	\$ 0	\$ 0
DEDICATED	\$ 0	\$ 0	\$ 0
FEDERAL FUNDS	\$ 0	\$ 0	\$ 0
OTHER (Specify)	\$ 0	\$ 0	\$ 0
<b>TOTAL</b>	<b>\$ 1,000</b>	<b>\$ 0</b>	<b>\$ 0</b>

4. Does your agency currently have sufficient funds to implement the proposed action? If not, how and when do you anticipate obtaining such funds?

The Board currently has sufficient funds budgeted and available to complete the promulgation process.

**B. COST SAVINGS TO LOCAL GOVERNMENTAL UNITS RESULTING FROM THE ACTION PROPOSED**

1. Provide an estimate of the anticipated impact of the proposed action on local governmental units, including adjustments in workload and paperwork requirements. Describe all data, assumptions and methods used in calculating this impact.

2. Indicate the source of funding of the local governmental unit that will be affected by these costs or savings.

We can discern no impact on local governmental units from the proposed rule.

**II. EFFECT ON REVENUE COLLECTIONS OF STATE AND LOCAL GOVERNMENTAL UNITS**

A. What increase (decrease) in revenues can be anticipated from the proposed action?

<u>SOURCE</u>	<u>FY 13-14</u>	<u>FY 14-15</u>	<u>FY 15-16</u>
STATE GENERAL FUND	\$ 0	\$ 0	\$ 0
AGENCY SELF-GENERATED	\$ 0	\$ 0	\$ 0
DEDICATED FUNDS	\$ 0	\$ 0	\$ 0
FEDERAL FUNDS	\$ 0	\$ 0	\$ 0
LOCAL FUNDS	\$ 0	\$ 0	\$ 0
<b>TOTAL</b>	<b>\$ 0</b>	<b>\$ 0</b>	<b>\$ 0</b>

B. Provide a narrative explanation of each increase or decrease in revenues shown in "A". Describe all data, assumptions, and methods used in calculating these increases or decreases.

We can discern no impact on the revenue collections of state and local governmental units from the proposed rule.

III. COSTS AND/OR ECONOMIC BENEFITS TO DIRECTLY AFFECTED PERSONS OR NON-GOVERNMENTAL GROUPS

- A. What persons or non-governmental groups would be directly affected by the proposed action? For each, provide an estimate and a narrative description of any effect on costs, including workload adjustments and additional paperwork (number of new forms, additional documentation, etc.), they may have to incur as a result of the proposed action.

The beneficiaries of the proposed rule are those physicians and pharmacists who elect to engage in collaborative drug therapy management activities. The proposed rule would reduce the amount of documentation required by eliminating the necessity for a formal CDTM agreement. Through its reduction on the number of restrictions on patient eligibility types, the proposed rule would also increase the number of patients for whom the physicians and pharmacists could collaborate on their drug therapy management.

Also provide an estimate and a narrative description of any impact on receipts and/or income (revenue) resulting from this rule or rule change to these groups.

We do not anticipate any impact on receipts or revenue resulting from this proposed rule.

IV. EFFECTS ON COMPETITION AND EMPLOYMENT

Identify and provide estimates of the impact of the proposed action on competition and employment in the public and private sectors. Include a summary of any data, assumptions and methods used in making these estimates.

We envision no impact on competition or employment.

  
\_\_\_\_\_  
Signature of Agency Head or Designee

**Malcolm J Broussard, Executive Director**  
Typed Name and Title of Agency Head or Designee

**June 20, 2013**  
\_\_\_\_\_  
Date of Signature