Modular Program Report

The following report(s) provides findings from an FDA-initiated query using its Mini-Sentinel pilot. While Mini-Sentinel queries may be undertaken to assess potential medical product safety risks, they may also be initiated for various other reasons. Some examples include determining a rate or count of an identified health outcome of interest, examining medical product use, exploring the feasibility of future, more detailed analyses within Mini-Sentinel, and seeking to better understand the capabilities of the Mini-Sentinel pilot.

Data obtained through Mini-Sentinel are intended to complement other types of evidence such as preclinical studies, clinical trials, postmarket studies, and adverse event reports, all of which are used by FDA to inform regulatory decisions regarding medical product safety. The information contained in this report is provided as part of FDA's commitment to place knowledge acquired from the Mini-Sentinel pilot in the public domain as soon as possible. Any public health actions taken by FDA regarding products involved in Mini-Sentinel queries will continue to be communicated through existing channels.

FDA wants to emphasize that the fact that FDA has initiated a query involving a medical product and is reporting findings related to that query does not mean that FDA is suggesting health care practitioners should change their prescribing practices for the medical product or that patients taking the medical product should stop using it. Patients who have questions about the use of an identified medical product should contact their health care practitioners.

The following report contains a description of the request, request specifications, and results from the modular program run(s).

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Overview

Request Description	FDA has requested execution of Modular Program #5 (MP5), version 2.0, to investigate chronic kidney disease (CKD) in the Mini-Sentinel Distributed Database (MSDD). This involved one run of MP5. The time window for the request is January 1, 2000 –December 31, 2012. The package was distributed to 18 Data Partners on February 15, 2013.
	Results provide counts of prevalent and incident CKD patients, total claims, eligible members, and member-days. CKD was defined using several different groups of diagnosis codes, which can be found in Appendix A. A CKD patient was considered new if he/she did not have a prior CKD diagnosis in the previous 183 days. The query period was January 1, 2000 to December 31, 2012.
Request ID	msy4_mpr16_v1
Specifications	Program parameter inputs and scenarios
Glossary	List of terms found in this report and their definitions
Table 1	Table displaying the number of prevalent and incident CKD patients, new starts, total claims, eligible members, member-days, and number of patients per 100,000 eligible members by algorithm used to define CKD and care setting - January 1, 2000 - December 31, 2012.
Figure 1	One figure displaying the information in the prior tab.
Table 2	Table displaying the number of prevalent and incident CKD patients, new starts, total claims, eligible members, member-days, and number of patients per 100,000 eligible members by algorithm used to define CKD, care setting, and age group - January 1, 2000 - December 31, 2012.
Table 3	Table displaying the number of prevalent and incident CKD patients, new starts, total claims, eligible members, member-days, and number of patients per 100,000 eligible members by algorithm used to define CKD, care setting, and sex - January 1, 2000 - December 31, 2012.
Table 4	Table displaying the number of prevalent and incident CKD patients, new starts, total claims, eligible members, member-days, and number of patients per 100,000 eligible members by algorithm used to define CKD, care setting, and year - January 1, 2000 - December 31, 2012.
Appendix A	List of diagnosis codes used to define Chronic Kidney Disease included in this request
Notes:	Please contact the Mini-Sentinel Operations Center (MSOC_Requests@harvardpilgrim.org) for questions and to provide comments/suggestions for future enhancements to this document.

Modular Program Specifications

Modular Program #5, version 2.0, was used to investigate prevalence and incidence of chronic kidney disease. The query period was from January 1, 2000 to December 31, 2012, and the enrollment gap was set at 45 days. Age groups were split as follows: Under 64, and 65+ years. In total, ten different scenarios were examined in this report with differing algorithms to define chronic kidney disease, and differing care settings. See below for a description of each of these scenarios.

		Drug/Exposure Criteria				
Scenario	Incident exposure	Incident w/ respect to (incidence criteria):	Washout (days)	Incidence Type*	Care Setting	Principal Diagnosis Indicator
1	CKD codes included in "Parker" Algorithm	All "Parker" Algorithm codes	183	Minimum	Any	NO
2	CKD codes included in "Parker" Algorithm	All "Parker" Algorithm codes	183	Minimum	Inpatient	NO
3	CKD codes included in "Romano" Algorithm	All "Romano" Algorithm codes	183	Minimum	Any	NO
4	CKD codes included in "Romano" Algorithm	All "Romano" Algorithm codes	183	Minimum	Inpatient	NO
5	CKD codes included in "Kern" Algorithm	All "Kern" Algorithm codes	183	Minimum	Any	NO
6	CKD codes included in "Kern" Algorithm	All "Kern" Algorithm codes	183	Minimum	Inpatient	NO
7	CKD codes included in "Quan" Algorithm	All "Quan" Algorithm codes	183	Minimum	Any	NO
8	CKD codes included in "Quan" Algorithm	All "Quan" Algorithm codes	183	Minimum	Inpatient	NO
9	CKD codes included in "So" Algorithm	All "So" Algorithm codes	183	Minimum	Any	NO
10	CKD codes included in "So" Algorithm	All "So" Algorithm codes	183	Minimum	Inpatient	NO

*A "minimum" incidence type for the exposure will only consider the first incident exposure (dispensings/procedures) for each member over the member's entire enrollment history. There can be at most one incident exposures (dispensings/procedures) per member. The enrollment requirement is based on the number of days in the washout.

Glossary of Terms in Modular Program 5*

Eligible Members (incidence-based cohort) - Number of members eligible for incident diagnosis (defined by the washout period) with medical coverage during the query period.

Eligible Members (prevalence-based cohort) - Number of members with at least one day of medical coverage during the query period.

Enrollment Gap - Number of days allowed between two consecutive enrollment periods without breaking a "continuously enrolled" sequence.

Incidence Type (drug/exposure) - *Minimum incidence type* will consider the first dispensing in the query period as a new start as long as it is the first dispensing in the user's entire available history. *Multiple incidence type* will use the washout period to establish incidence, however Multiple will consider all qualifying incident dispensings as new starts.

Member-Days (incidence-based cohort) - Sum of all days of enrollment with medical coverage in the query period preceded by a washout period.

Member-Days (prevalence-based cohort) - Sum of all days members are enrolled with medical coverage during the query period.

New Starts- Number of incident diagnoses during the query period. Patient must have no prior diagnoses in the washout period. For a minimum incidence type, an individual may have no more than one new start. For a multiple washout type, an individual may have more than one new start.

New Patients - Number of members with incident diagnosis during the query period. Member must have no evidence of diagnosis of interest (defined by incidence criteria) in the prior washout period. A patient may only be counted once in a query period.

Query Period - Period in which the modular program looks for diagnoses of interest.

Washout Period - Number of days a patient is required to have no evidence of prior diagnosis and continuous medical coverage.

*all terms may not be used in this report

Table 1. Summary of Chronic Kidney Disease in the MSDD between January 1, 2000 and December 31, 2012, by Algorithm Used to Define Chronic Kidney Disease and Care Setting

	Prevalent					Incident					
	Patients	Number of Claims	Eligible Members	Member-Days	Patients per 100K Eligible Members	New Patients	New Claims	Number of New Claims	Eligible Members	Member-Days	New Patients per 100K Eligible Members
"Kern" Algorithm											
Any Care Setting	10,568,445	82,188,551	165,645,517	161,304,620,851	6,380	7,388,931	7,388,939	38,658,724	134,766,425	122,202,033,997	5,483
Inpatient Care Setting	3,119,019	7,403,941	165,645,517	161,304,620,851	1,883	2,495,368	2,495,371	5,577,204	137,002,294	128,770,429,433	1,821
"Parker" Algorithm											
Any Care Setting	2,804,483	42,930,266	165,645,517	161,304,620,851	1,693	2,019,080	2,019,085	19,132,546	136,824,241	128,834,520,139	1,476
Inpatient Care Setting	1,002,689	2,748,309	165,645,517	161,304,620,851	605	830,534	830,536	2,095,010	137,354,072	130,355,506,551	605
"Quan" Algorithm											
Any Care Setting	3,183,684	44,936,885	165,645,517	161,304,620,851	1,922	2,288,237	2,288,242	19,733,998	136,732,864	128,539,791,612	1,674
Inpatient Care Setting	1,164,419	3,068,692	165,645,517	161,304,620,851	703	961,208	961,210	2,339,614	137,332,096	130,261,977,106	700
"Romano" Algorithm											
Any Care Setting	3,282,976	45,741,093	165,645,517	161,304,620,851	1,982	2,351,139	2,351,144	20,084,626	136,701,042	128,400,792,280	1,720
Inpatient Care Setting	1,201,908	3,159,784	165,645,517	161,304,620,851	726	992,692	992,694	2,411,655	137,327,095	130,217,301,382	723
"So" Algorithm											
Any Care Setting	3,774,210	46,132,142	165,645,517	161,304,620,851	2,278	2,758,928	2,758,932	20,623,119	136,625,795	127,999,840,388	2,019
Inpatient Care Setting	1,393,299	3,483,539	165,645,517	161,304,620,851	841	1,144,779	1,144,781	2,644,020	137,290,816	130,023,134,007	834

Figure 1. Number of Prevalent and Incident CKD Patients per 100,000 Eligible Members between January 1, 2000 and December 31, 2011 by Algorithm used to define CKD and Care Setting
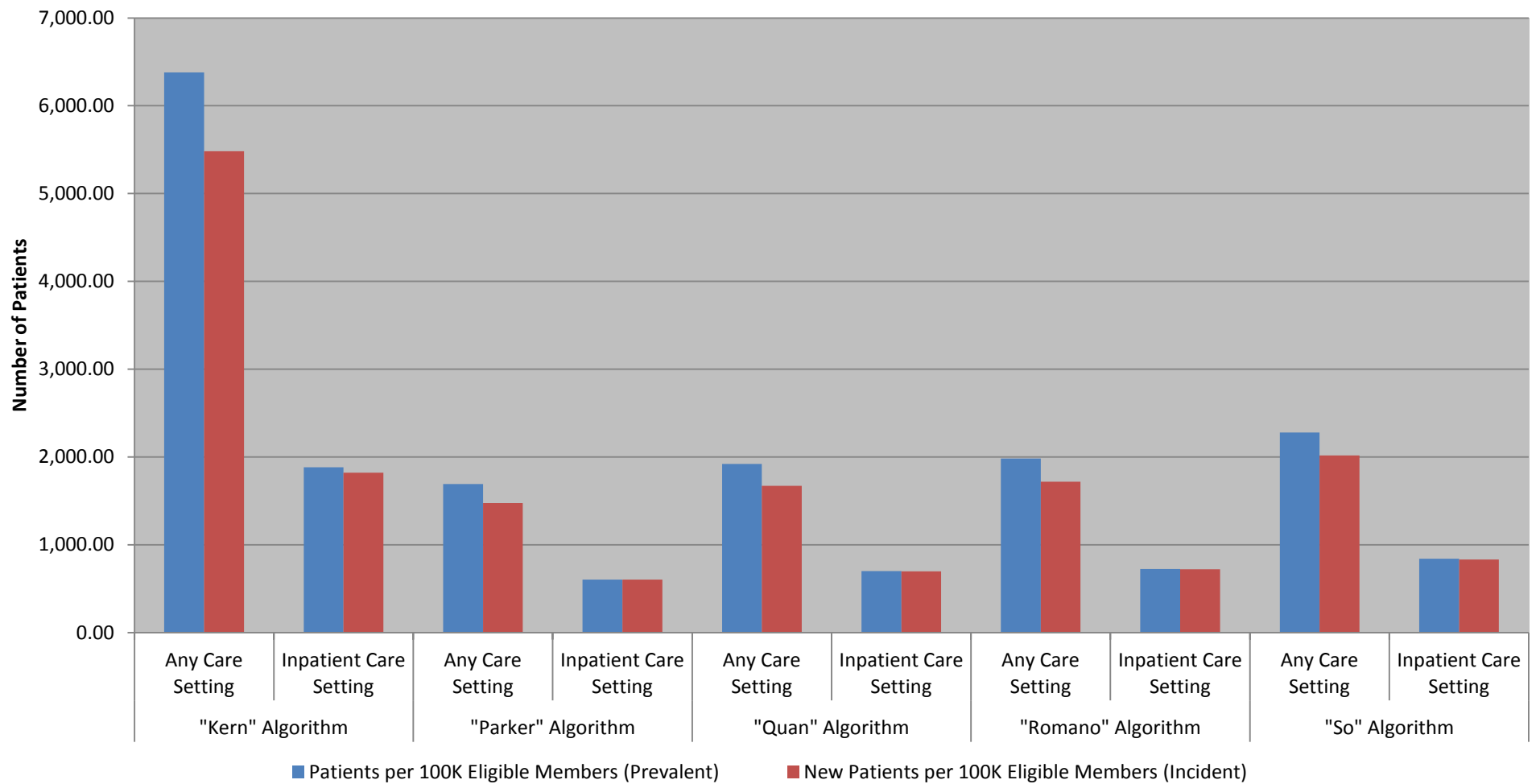
Table 2. Summary of Chronic Kidney Disease in the MSDD between January 1, 2000 and December 31, 2012, by Algorithm Used to Define Chronic Kidney Disease, Care Setting, and Age Group

	Prevalent					Incident					
	Patients	Number of Claims	Eligible Members	Member-Days	Patients per 100K Eligible Members	New Patients	New Claims	Number of New Claims	Eligible Members	Member-Days	New Patients per 100K Eligible Members
"Kern" Algorithm											
Any Care Setting											
Under 65 Years	6,785,144	42,567,151	153,905,532	142,724,348,827	4,409	4,676,348	4,676,355	19,599,176	124,336,628	109,352,304,487	3,761
65 +Years	3,965,455	39,621,400	15,472,050	18,580,272,024	25,630	2,712,583	2,712,584	17,811,287	12,799,180	12,849,729,510	21,193
Inpatient Care Setting											
Under 65 Years	1,415,710	2,858,168	153,905,532	142,724,348,827	920	1,068,665	1,068,668	2,016,760	125,842,192	113,605,846,311	849
65 +Years	1,731,371	4,545,773	15,472,050	18,580,272,024	11,190	1,426,703	1,426,703	3,483,886	13,831,591	15,164,583,122	10,315
"Parker" Algorithm											
Any Care Setting											
Under 65 Years	1,045,639	18,482,298	153,905,532	142,724,348,827	679	717,711	717,714	6,972,583	125,845,236	113,884,718,054	570
65 +Years	1,822,220	24,447,968	15,472,050	18,580,272,024	11,777	1,301,369	1,301,371	11,404,227	13,643,341	14,949,802,085	9,538
Inpatient Care Setting											
Under 65 Years	289,531	833,744	153,905,532	142,724,348,827	188	222,528	222,530	580,082	126,062,399	114,435,120,917	177
65 +Years	723,795	1,914,565	15,472,050	18,580,272,024	4,678	608,006	608,006	1,481,990	14,034,725	15,920,385,634	4,332
"Quan" Algorithm											
Any Care Setting											
Under 65 Years	1,256,094	19,331,928	153,905,532	142,724,348,827	816	865,777	865,780	7,200,569	125,793,372	113,726,305,730	688
65 +Years	1,996,143	25,604,957	15,472,050	18,580,272,024	12,902	1,422,460	1,422,462	11,770,325	13,589,766	14,813,485,882	10,467
Inpatient Care Setting											
Under 65 Years	355,717	942,666	153,905,532	142,724,348,827	231	273,776	273,778	660,003	126,051,518	114,396,515,529	217
65 +Years	820,150	2,126,026	15,472,050	18,580,272,024	5,301	687,432	687,432	1,645,215	14,019,184	15,865,461,577	4,904
"Romano" Algorithm											
Any Care Setting											
Under 65 Years	1,324,734	19,762,426	153,905,532	142,724,348,827	861	911,489	911,492	7,390,494	125,774,239	113,650,826,893	725
65 +Years	2,032,933	25,978,667	15,472,050	18,580,272,024	13,139	1,439,650	1,439,652	11,877,929	13,568,419	14,749,965,387	10,610
Inpatient Care Setting											
Under 65 Years	376,397	987,432	153,905,532	142,724,348,827	245	290,550	290,552	692,844	126,048,338	114,374,787,419	231
65 +Years	838,165	2,172,352	15,472,050	18,580,272,024	5,417	702,142	702,142	1,680,024	14,014,611	15,842,513,963	5,010

Table 2. Summary of Chronic Kidney Disease in the MSDD between January 1, 2000 and December 31, 2012, by Algorithm Used to Define Chronic Kidney Disease, Care Setting, and Age Group

	Prevalent					Incident					
	Patients	Number of Claims	Eligible Members	Member-Days	Patients per 100K Eligible Members	New Patients	New Claims	Number of New Claims	Eligible Members	Member-Days	New Patients per 100K Eligible Members
"So" Algorithm											
Any Care Setting											
Under 65 Years	1,676,932	20,075,146	153,905,532	142,724,348,827	1,090	1,201,439	1,201,442	7,797,205	125,720,673	113,396,395,805	956
65 +Years	2,171,728	26,056,996	15,472,050	18,580,272,024	14,036	1,557,489	1,557,490	12,029,256	13,526,467	14,603,444,583	11,514
Inpatient Care Setting											
Under 65 Years	479,782	1,143,134	153,905,532	142,724,348,827	312	371,506	371,508	800,208	126,028,332	114,287,015,024	295
65 +Years	928,054	2,340,405	15,472,050	18,580,272,024	5,998	773,273	773,273	1,800,832	13,986,950	15,736,118,983	5,529

Table 3. Summary of Chronic Kidney Disease in the MSDD between January 1, 2000 and December 31, 2012, by Algorithm Used to Define Chronic Kidney Disease, Care Setting, and Sex

	Prevalent					Incident					
	Patients	Number of Claims	Eligible Members	Member-Days	Patients per 100K Eligible Members	New Patients	New Claims	Number of New Claims	Eligible Members	Member-Days	New Patients per 100K Eligible Members
"Kern" Algorithm											
Any Care Setting											
Female	5,496,669	39,240,966	84,210,614	83,337,068,820	6,527	3,881,473	3,881,475	18,906,100	68,937,483	63,294,118,476	5,630
Male	5,065,573	42,908,121	81,297,101	77,796,206,799	6,231	3,503,064	3,503,070	19,734,677	65,703,225	58,776,663,300	5,332
Unknown	6,200	39,450	137,802	171,345,232	4,499	4,391	4,391	17,933	125,717	131,252,221	3,493
Inpatient Care Setting											
Female	1,575,715	3,637,778	84,210,614	83,337,068,820	1,871	1,267,862	1,267,863	2,754,337	70,076,121	66,720,577,152	1,809
Male	1,541,856	3,763,757	81,297,101	77,796,206,799	1,897	1,226,389	1,226,391	2,821,066	66,799,304	61,914,559,197	1,836
Unknown	1,445	2,403	137,802	171,345,232	1,049	1,114	1,114	1,798	126,869	135,293,084	878
"Parker" Algorithm											
Any Care Setting											
Female	1,344,672	19,394,253	84,210,614	83,337,068,820	1,597	990,805	990,805	8,973,005	70,018,390	66,820,739,040	1,415
Male	1,459,042	23,516,802	81,297,101	77,796,206,799	1,795	1,027,714	1,027,719	10,153,472	66,678,878	61,877,979,829	1,541
Unknown	768	19,208	137,802	171,345,232	557	560	560	6,066	126,973	135,801,270	441
Inpatient Care Setting											
Female	452,450	1,253,047	84,210,614	83,337,068,820	537	379,127	379,127	961,653	70,260,175	67,580,288,553	540
Male	549,972	1,494,694	81,297,101	77,796,206,799	676	451,177	451,179	1,132,914	66,966,798	62,639,021,361	674
Unknown	267	568	137,802	171,345,232	194	230	230	443	127,099	136,196,637	181
"Quan" Algorithm											
Any Care Setting											
Female	1,534,427	20,343,378	84,210,614	83,337,068,820	1,822	1,128,330	1,128,330	9,303,522	69,974,968	66,670,021,660	1,612
Male	1,648,306	24,573,720	81,297,101	77,796,206,799	2,028	1,159,206	1,159,211	10,423,988	66,630,953	61,734,110,038	1,740
Unknown	950	19,784	137,802	171,345,232	689	700	700	6,485	126,943	135,659,914	551
Inpatient Care Setting											
Female	530,372	1,403,572	84,210,614	83,337,068,820	630	442,801	442,801	1,077,427	70,249,986	67,533,707,582	630
Male	633,717	1,664,455	81,297,101	77,796,206,799	780	518,123	518,125	1,261,665	66,955,018	62,592,110,981	774
Unknown	330	665	137,802	171,345,232	239	284	284	522	127,092	136,158,543	223

Table 3. Summary of Chronic Kidney Disease in the MSDD between January 1, 2000 and December 31, 2012, by Algorithm Used to Define Chronic Kidney Disease, Care Setting, and Sex

	Prevalent					Incident					
	Patients	Number of Claims	Eligible Members	Member-Days	Patients per 100K Eligible Members	New Patients	New Claims	Number of New Claims	Eligible Members	Member-Days	New Patients per 100K Eligible Members
"Romano" Algorithm											
Any Care Setting											
Female	1,581,949	20,747,528	84,210,614	83,337,068,820	1,879	1,157,816	1,157,816	9,469,261	69,959,199	66,603,606,198	1,655
Male	1,700,022	24,973,530	81,297,101	77,796,206,799	2,091	1,192,582	1,192,587	10,608,749	66,614,917	61,661,573,360	1,790
Unknown	1,004	20,032	137,802	171,345,232	729	740	740	6,613	126,926	135,612,722	583
Inpatient Care Setting											
Female	549,693	1,450,549	84,210,614	83,337,068,820	653	458,839	458,839	1,113,915	70,247,267	67,510,861,071	653
Male	651,869	1,708,544	81,297,101	77,796,206,799	802	533,555	533,557	1,297,193	66,952,737	62,570,294,337	797
Unknown	346	691	137,802	171,345,232	251	298	298	547	127,091	136,145,974	234
"So" Algorithm											
Any Care Setting											
Female	1,874,230	21,050,403	84,210,614	83,337,068,820	2,226	1,400,183	1,400,183	9,830,565	69,914,577	66,362,280,246	2,003
Male	1,898,667	25,061,279	81,297,101	77,796,206,799	2,335	1,357,764	1,357,768	10,785,717	66,584,334	61,502,212,027	2,039
Unknown	1,312	20,455	137,802	171,345,232	952	980	980	6,832	126,884	135,348,115	772
Inpatient Care Setting											
Female	641,935	1,604,852	84,210,614	83,337,068,820	762	533,084	533,084	1,226,783	70,230,698	67,418,183,300	759
Male	750,948	1,877,895	81,297,101	77,796,206,799	924	611,342	611,344	1,416,617	66,933,036	62,468,874,289	913
Unknown	415	791	137,802	171,345,232	301	352	352	619	127,082	136,076,418	277

Table 4. Summary of Chronic Kidney Disease in the MSDD between January 1, 2000 and December 31, 2012, by Algorithm Used to Define Chronic Kidney Disease, Care Setting, and Year

	Prevalent					Incident					
	Patients	Number of Claims	Eligible Members	Member-Days	Patients per 100K Eligible Members	New Patients	New Claims	Number of New Claims	Eligible Members	Member-Days	New Patients per 100K Eligible Members
"Kern" Algorithm											
Any Care Setting											
2000	186,659	676,311	9,558,453	3,017,441,885	1,953	66,042	66,042	114,253	8,030,644	1,356,665,221	822
2001	201,004	737,644	9,468,317	3,028,814,659	2,123	116,957	116,957	239,422	8,553,661	2,669,053,859	1,367
2002	222,684	815,193	9,458,216	3,022,847,768	2,354	114,280	114,280	231,047	8,513,698	2,645,175,111	1,342
2003	251,847	912,078	9,369,937	2,990,510,784	2,688	118,621	118,621	236,609	8,382,723	2,597,291,169	1,415
2004	797,414	3,243,022	30,090,321	9,047,049,444	2,650	299,490	299,490	570,473	24,353,599	5,134,934,935	1,230
2005	904,435	3,766,426	33,403,560	10,008,528,668	2,708	450,065	450,066	959,186	28,507,627	8,061,133,576	1,579
2006	1,037,518	4,232,200	34,648,372	10,439,126,332	2,994	491,781	491,783	1,040,172	29,450,843	8,549,938,083	1,670
2007	1,366,728	5,951,591	38,766,091	11,391,175,086	3,526	535,793	535,794	1,126,757	32,376,595	8,882,899,665	1,655
2008	2,907,134	13,043,156	82,970,005	25,077,563,671	3,504	1,090,328	1,090,329	2,380,976	67,714,909	15,346,180,061	1,610
2009	3,086,600	14,502,322	82,514,889	25,377,639,414	3,741	1,397,745	1,397,745	3,335,701	70,911,950	20,649,319,210	1,971
2010	3,177,560	15,320,937	81,902,038	25,162,748,292	3,880	1,272,717	1,272,718	3,012,236	69,508,496	20,273,328,118	1,831
2011	3,106,127	14,248,841	82,078,203	24,870,588,364	3,784	1,113,961	1,113,963	2,602,895	68,959,187	19,901,843,521	1,615
2012	1,409,142	4,738,830	49,266,519	7,870,586,484	2,860	321,151	321,151	639,212	38,337,761	6,134,271,468	838
Inpatient Care Setting											
2000	57,399	92,350	9,558,453	3,017,441,885	601	23,785	23,785	30,865	8,110,623	1,374,297,862	293
2001	63,306	100,683	9,468,317	3,028,814,659	669	45,300	45,300	63,221	8,677,442	2,722,858,604	522
2002	70,118	111,541	9,458,216	3,022,847,768	741	46,285	46,285	63,177	8,703,410	2,720,445,307	532
2003	78,445	123,696	9,369,937	2,990,510,784	837	49,148	49,148	65,979	8,627,613	2,691,061,092	570
2004	211,027	319,950	30,090,321	9,047,049,444	701	103,180	103,180	133,523	24,892,266	5,298,515,412	415
2005	233,849	352,344	33,403,560	10,008,528,668	700	157,241	157,241	209,344	29,257,992	8,349,676,461	537
2006	256,560	388,144	34,648,372	10,439,126,332	740	167,082	167,082	220,879	30,430,399	8,920,568,827	549
2007	317,421	565,208	38,766,091	11,391,175,086	819	177,432	177,432	238,847	33,717,981	9,347,985,386	526
2008	628,231	1,115,936	82,970,005	25,077,563,671	757	338,917	338,919	560,740	70,033,178	16,099,543,663	484
2009	668,558	1,224,587	82,514,889	25,377,639,414	810	448,285	448,285	717,629	73,853,582	21,768,140,475	607
2010	694,272	1,307,635	81,902,038	25,162,748,292	848	437,599	437,599	711,529	73,034,484	21,561,024,980	599
2011	642,534	1,255,323	82,078,203	24,870,588,364	783	384,831	384,832	648,244	72,945,881	21,308,476,667	528
2012	224,253	446,544	49,266,519	7,870,586,484	455	116,283	116,283	191,787	40,998,386	6,607,834,697	284

Table 4. Summary of Chronic Kidney Disease in the MSDD between January 1, 2000 and December 31, 2012, by Algorithm Used to Define Chronic Kidney Disease, Care Setting, and Year

	Prevalent					Incident					
	Patients	Number of Claims	Eligible Members	Member-Days	Patients per 100K Eligible Members	New Patients	New Claims	Number of New Claims	Eligible Members	Member-Days	New Patients per 100K Eligible Members
"Parker" Algorithm											
Any Care Setting											
2000	28,344	255,520	9,558,453	3,017,441,885	297	7,354	7,354	16,284	8,118,830	1,376,862,722	91
2001	30,961	275,398	9,468,317	3,028,814,659	327	14,376	14,376	43,822	8,699,321	2,733,946,974	165
2002	35,286	301,723	9,458,216	3,022,847,768	373	14,998	14,998	45,156	8,745,687	2,738,303,280	171
2003	40,805	331,523	9,369,937	2,990,510,784	435	16,581	16,581	45,458	8,687,377	2,714,730,252	191
2004	120,450	1,334,351	30,090,321	9,047,049,444	400	40,022	40,022	99,247	24,983,496	5,332,423,093	160
2005	161,862	1,651,389	33,403,560	10,008,528,668	485	77,341	77,341	219,124	29,387,946	8,403,174,199	263
2006	256,921	2,026,716	34,648,372	10,439,126,332	742	136,162	136,163	347,926	30,590,316	8,975,694,475	445
2007	458,629	3,284,368	38,766,091	11,391,175,086	1,183	195,240	195,240	436,552	33,813,326	9,384,421,207	577
2008	877,655	6,727,859	82,970,005	25,077,563,671	1,058	319,039	319,040	779,060	69,974,961	16,086,401,369	456
2009	1,000,851	7,786,599	82,514,889	25,377,639,414	1,213	385,815	385,816	1,073,449	73,747,611	21,732,954,809	523
2010	1,098,480	8,462,468	81,902,038	25,162,748,292	1,341	360,231	360,232	978,282	72,913,731	21,524,163,698	494
2011	1,157,884	7,795,296	82,078,203	24,870,588,364	1,411	336,635	336,636	853,803	72,813,016	21,262,193,707	462
2012	675,188	2,697,056	49,266,519	7,870,586,484	1,370	115,286	115,286	218,939	40,780,922	6,569,250,354	283
Inpatient Care Setting											
2000	10,371	20,166	9,558,453	3,017,441,885	109	4,140	4,140	5,770	8,132,277	1,379,471,897	51
2001	11,091	20,612	9,468,317	3,028,814,659	117	7,273	7,273	11,280	8,715,858	2,740,655,194	83
2002	12,174	22,747	9,458,216	3,022,847,768	129	7,247	7,247	11,086	8,768,252	2,747,074,434	83
2003	13,371	24,706	9,369,937	2,990,510,784	143	7,578	7,578	11,133	8,715,839	2,725,738,302	87
2004	40,597	74,197	30,090,321	9,047,049,444	135	17,922	17,922	25,115	25,050,857	5,352,632,579	72
2005	56,163	96,004	33,403,560	10,008,528,668	168	38,282	38,282	54,434	29,479,468	8,438,378,582	130
2006	83,889	139,368	34,648,372	10,439,126,332	242	57,666	57,666	80,595	30,715,190	9,029,037,906	188
2007	130,075	244,657	38,766,091	11,391,175,086	336	74,765	74,765	106,692	34,066,353	9,472,259,104	219
2008	218,556	418,033	82,970,005	25,077,563,671	263	119,715	119,717	200,033	70,520,058	16,270,971,200	170
2009	239,331	470,384	82,514,889	25,377,639,414	290	153,672	153,672	248,465	74,472,236	22,012,048,897	206
2010	256,226	516,710	81,902,038	25,162,748,292	313	153,745	153,745	251,246	73,792,720	21,848,981,921	208
2011	247,418	506,126	82,078,203	24,870,588,364	301	140,902	140,902	233,577	73,830,586	21,629,132,296	191
2012	97,777	194,599	49,266,519	7,870,586,484	198	47,627	47,627	75,262	41,554,679	6,709,124,239	115

Table 4. Summary of Chronic Kidney Disease in the MSDD between January 1, 2000 and December 31, 2012, by Algorithm Used to Define Chronic Kidney Disease, Care Setting, and Year

	Prevalent					Incident					
	Patients	Number of Claims	Eligible Members	Member-Days	Patients per 100K Eligible Members	New Patients	New Claims	Number of New Claims	Eligible Members	Member-Days	New Patients per 100K Eligible Members
"Quan" Algorithm											
Any Care Setting											
2000	37,654	274,432	9,558,453	3,017,441,885	394	10,668	10,668	20,573	8,113,758	1,375,737,867	131
2001	41,392	293,398	9,468,317	3,028,814,659	437	21,023	21,023	52,754	8,691,428	2,730,349,571	242
2002	46,194	320,766	9,458,216	3,022,847,768	488	21,151	21,151	51,919	8,733,025	2,733,230,179	242
2003	52,448	351,729	9,369,937	2,990,510,784	560	22,636	22,636	52,946	8,670,996	2,708,460,706	261
2004	155,826	1,418,848	30,090,321	9,047,049,444	518	53,958	53,958	116,813	24,950,929	5,322,203,308	216
2005	195,316	1,737,716	33,403,560	10,008,528,668	585	94,225	94,225	243,467	29,344,788	8,386,604,457	321
2006	293,236	2,128,321	34,648,372	10,439,126,332	846	153,801	153,802	369,014	30,539,218	8,957,162,717	504
2007	499,619	3,422,268	38,766,091	11,391,175,086	1,289	209,907	209,907	459,847	33,749,224	9,362,761,589	622
2008	973,436	7,070,978	82,970,005	25,077,563,671	1,173	356,933	356,934	847,444	69,876,378	16,054,103,687	511
2009	1,100,311	8,158,688	82,514,889	25,377,639,414	1,333	437,784	437,785	1,174,262	73,624,471	21,685,363,183	595
2010	1,196,096	8,828,233	81,902,038	25,162,748,292	1,460	405,913	405,914	1,066,083	72,766,544	21,469,691,943	558
2011	1,247,705	8,131,855	82,078,203	24,870,588,364	1,520	375,068	375,069	927,215	72,647,193	21,203,072,652	516
2012	709,276	2,799,653	49,266,519	7,870,586,484	1,440	125,170	125,170	236,447	40,678,016	6,551,049,753	308
Inpatient Care Setting											
2000	12,990	22,511	9,558,453	3,017,441,885	136	5,439	5,439	7,118	8,131,408	1,379,250,577	67
2001	13,996	23,001	9,468,317	3,028,814,659	148	9,934	9,934	14,056	8,714,115	2,739,773,751	114
2002	15,020	24,846	9,458,216	3,022,847,768	159	9,823	9,823	13,631	8,765,055	2,745,745,617	112
2003	16,052	25,846	9,369,937	2,990,510,784	171	10,168	10,168	13,508	8,711,555	2,724,063,907	117
2004	51,655	86,326	30,090,321	9,047,049,444	172	23,914	23,914	31,653	25,041,934	5,349,781,158	95
2005	67,236	108,801	33,403,560	10,008,528,668	201	47,419	47,419	65,760	29,467,267	8,433,347,212	161
2006	95,345	155,564	34,648,372	10,439,126,332	275	65,784	65,784	91,305	30,699,283	9,022,957,400	214
2007	142,696	267,566	38,766,091	11,391,175,086	368	82,061	82,061	116,238	34,046,990	9,465,452,506	241
2008	249,324	472,570	82,970,005	25,077,563,671	300	137,077	137,079	229,159	70,491,902	16,261,104,414	194
2009	272,228	529,577	82,514,889	25,377,639,414	330	178,064	178,064	287,536	74,435,678	21,997,182,656	239
2010	289,288	576,796	81,902,038	25,162,748,292	353	176,974	176,974	288,374	73,746,922	21,831,279,312	240
2011	277,116	562,232	82,078,203	24,870,588,364	338	161,153	161,153	266,822	73,776,566	21,609,304,473	218
2012	107,278	213,056	49,266,519	7,870,586,484	218	53,398	53,398	84,564	41,519,737	6,702,734,123	129

Table 4. Summary of Chronic Kidney Disease in the MSDD between January 1, 2000 and December 31, 2012, by Algorithm Used to Define Chronic Kidney Disease, Care Setting, and Year

	Prevalent					Incident					
	Patients	Number of Claims	Eligible Members	Member-Days	Patients per 100K Eligible Members	New Patients	New Claims	Number of New Claims	Eligible Members	Member-Days	New Patients per 100K Eligible Members
"Romano" Algorithm											
Any Care Setting											
2000	42,375	286,105	9,558,453	3,017,441,885	443	12,283	12,283	22,344	8,110,857	1,375,092,975	151
2001	46,409	305,430	9,468,317	3,028,814,659	490	23,543	23,543	55,445	8,687,008	2,728,413,957	271
2002	52,690	333,763	9,458,216	3,022,847,768	557	24,307	24,307	55,639	8,726,478	2,730,464,545	279
2003	62,554	371,131	9,369,937	2,990,510,784	668	28,106	28,106	60,156	8,661,778	2,704,377,350	324
2004	177,312	1,457,973	30,090,321	9,047,049,444	589	65,018	65,018	130,611	24,934,105	5,315,681,567	261
2005	221,410	1,791,045	33,403,560	10,008,528,668	663	104,958	104,958	256,751	29,317,898	8,375,377,259	358
2006	321,644	2,188,606	34,648,372	10,439,126,332	928	162,295	162,296	378,424	30,504,479	8,943,999,958	532
2007	530,217	3,492,641	38,766,091	11,391,175,086	1,368	212,418	212,418	460,418	33,702,342	9,348,376,370	630
2008	1,016,564	7,186,581	82,970,005	25,077,563,671	1,225	363,171	363,172	851,009	69,822,912	16,036,228,150	520
2009	1,142,084	8,274,365	82,514,889	25,377,639,414	1,384	443,834	443,835	1,179,675	73,568,228	21,665,423,120	603
2010	1,236,967	8,951,737	81,902,038	25,162,748,292	1,510	411,179	411,180	1,070,920	72,710,286	21,449,912,855	566
2011	1,282,996	8,253,754	82,078,203	24,870,588,364	1,563	376,111	376,112	930,838	72,590,214	21,183,917,882	518
2012	730,173	2,847,962	49,266,519	7,870,586,484	1,482	123,916	123,916	233,249	40,633,700	6,543,526,292	305
Inpatient Care Setting											
2000	15,057	25,793	9,558,453	3,017,441,885	158	6,299	6,299	8,229	8,130,335	1,378,994,058	77
2001	16,328	26,634	9,468,317	3,028,814,659	172	11,575	11,575	16,271	8,712,282	2,738,899,844	133
2002	17,723	28,906	9,458,216	3,022,847,768	187	11,609	11,609	15,945	8,762,011	2,744,446,051	132
2003	19,940	31,618	9,369,937	2,990,510,784	213	12,744	12,744	16,912	8,707,313	2,722,247,559	146
2004	57,886	95,434	30,090,321	9,047,049,444	192	27,609	27,609	36,371	25,035,260	5,347,135,783	110
2005	73,923	118,794	33,403,560	10,008,528,668	221	51,393	51,393	70,839	29,457,979	8,429,525,178	174
2006	101,046	164,090	34,648,372	10,439,126,332	292	68,495	68,495	94,369	30,687,865	9,018,628,536	223
2007	147,686	275,190	38,766,091	11,391,175,086	381	83,637	83,637	117,651	34,034,265	9,460,984,194	246
2008	256,262	482,388	82,970,005	25,077,563,671	309	140,131	140,133	232,417	70,478,255	16,256,163,413	199
2009	278,733	538,670	82,514,889	25,377,639,414	338	181,263	181,263	290,673	74,420,605	21,991,592,093	244
2010	295,658	585,830	81,902,038	25,162,748,292	361	180,181	180,181	291,893	73,730,913	21,825,350,850	244
2011	282,799	570,475	82,078,203	24,870,588,364	345	163,699	163,699	269,643	73,759,424	21,603,156,074	222
2012	109,491	215,962	49,266,519	7,870,586,484	222	54,057	54,057	85,006	41,506,078	6,700,177,749	130

Table 4. Summary of Chronic Kidney Disease in the MSDD between January 1, 2000 and December 31, 2012, by Algorithm Used to Define Chronic Kidney Disease, Care Setting, and Year

	Prevalent					Incident					
	Patients	Number of Claims	Eligible Members	Member-Days	Patients per 100K Eligible Members	New Patients	New Claims	Number of New Claims	Eligible Members	Member-Days	New Patients per 100K Eligible Members
"So" Algorithm											
Any Care Setting											
2000	49,031	298,310	9,558,453	3,017,441,885	513	15,561	15,561	26,513	8,107,799	1,374,245,836	192
2001	51,431	319,187	9,468,317	3,028,814,659	543	29,057	29,057	62,191	8,680,836	2,725,424,423	335
2002	58,271	355,550	9,458,216	3,022,847,768	616	30,382	30,382	64,137	8,715,634	2,725,793,459	349
2003	66,341	391,629	9,369,937	2,990,510,784	708	32,535	32,535	66,608	8,646,498	2,698,529,886	376
2004	202,387	1,513,418	30,090,321	9,047,049,444	673	77,522	77,522	147,000	24,902,737	5,305,827,166	311
2005	248,117	1,842,275	33,403,560	10,008,528,668	743	131,343	131,343	287,746	29,275,385	8,357,634,147	449
2006	346,889	2,223,058	34,648,372	10,439,126,332	1,001	187,932	187,933	412,526	30,443,264	8,919,016,695	617
2007	550,361	3,478,315	38,766,091	11,391,175,086	1,420	238,126	238,126	485,147	33,630,464	9,320,346,645	708
2008	1,090,314	7,208,677	82,970,005	25,077,563,671	1,314	418,284	418,285	922,831	69,708,567	15,995,197,345	600
2009	1,217,854	8,313,293	82,514,889	25,377,639,414	1,476	520,220	520,220	1,285,409	73,412,589	21,600,930,559	709
2010	1,314,538	9,007,835	81,902,038	25,162,748,292	1,605	487,066	487,067	1,173,393	72,506,362	21,370,028,677	672
2011	1,356,852	8,314,434	82,078,203	24,870,588,364	1,653	445,991	445,992	1,022,673	72,342,764	21,091,871,213	616
2012	747,228	2,866,161	49,266,519	7,870,586,484	1,517	144,909	144,909	262,296	40,480,527	6,514,994,337	358
Inpatient Care Setting											
2000	20,760	38,107	9,558,453	3,017,441,885	217	8,473	8,473	11,255	8,127,400	1,378,309,357	104
2001	23,265	41,186	9,468,317	3,028,814,659	246	15,986	15,986	22,920	8,707,379	2,736,614,063	184
2002	25,801	45,205	9,458,216	3,022,847,768	273	16,468	16,468	22,987	8,753,598	2,740,896,962	188
2003	28,864	49,459	9,369,937	2,990,510,784	308	17,714	17,714	23,947	8,695,370	2,717,516,696	204
2004	80,833	131,726	30,090,321	9,047,049,444	269	38,689	38,689	50,162	25,013,498	5,339,612,722	155
2005	96,257	153,626	33,403,560	10,008,528,668	288	65,253	65,253	87,155	29,427,026	8,416,973,232	222
2006	127,151	201,876	34,648,372	10,439,126,332	367	85,716	85,716	115,683	30,648,303	9,002,157,510	280
2007	158,089	283,397	38,766,091	11,391,175,086	408	87,073	87,073	117,705	33,984,363	9,443,952,281	256
2008	288,892	514,411	82,970,005	25,077,563,671	348	157,741	157,743	248,005	70,419,095	16,235,180,378	224
2009	312,262	573,282	82,514,889	25,377,639,414	378	205,278	205,278	313,229	74,348,234	21,962,883,470	276
2010	330,260	622,425	81,902,038	25,162,748,292	403	203,456	203,456	313,156	73,644,760	21,792,371,253	276
2011	313,472	602,628	82,078,203	24,870,588,364	382	183,252	183,252	287,261	73,659,920	21,566,835,239	249
2012	119,121	226,211	49,266,519	7,870,586,484	242	59,680	59,680	90,166	41,449,481	6,689,830,844	144

Appendix A. List of ICD-9-CM Diagnosis Codes used to Define Chronic Kidney Disease included in this Request

"Parker" Algorithm

585	V45.1	V56.2	V56.32
792.5	V56.0	V56.31	V56.8

"Romano" Algorithm

582	583	585	586	587

"Kern" Algorithm

403.11	274.1	583	403.01	590.1	446.0	236.91	592	753.11
403.91	403.10	590.0	404.00	590.2	446.2	239.5	593.0	753.15
404.12	403.90	593.6	404.01	590.3	446.4	040.1	593.1	753.16
404.13	404.10	593.9	404.02	590.8	446.6	447.3	593.2	753.17
404.92	404.11	753.12	404.03	593.81	710.0	589	593.3	753.19
404.93	404.90	753.13	405.01	866	710.1	591	593.82	753.2
585	404.91	753.14	453.3	203.0	189.0	593.4	593.89	753.3
586	581	250.4	580	277.3	189.1	593.5	753.0	
587	582	403.00	584	287.0	233.9	593.7	753.10	

"Quan" Algorithm

582	583.2	583.4	583.7	586
583.0	583.3	583.6	585	588
583.1				

"So" Algorithm

585	404	V45.1
403	996.7	