The Department of Health and Human Services requests public comment about the following proposed regulations for Exchanges (released July 11, 2011). **COMMENTS ARE DUE BY SEPTEMBER 28, 2011.**

Page numbers refer to the document "HS 45 CFR Parts 155 and 156, PPACA: Establishment of Exchanges and Qualified Health Plans" available here.
Note: SHOP = Small Business Health Options Program; QHP = Qualified Health Plan; PBM=Pharmacy Benefit Manager

Page	HHS seeks comment on…	Section	Section page
23	States must notify HHS before significant changes are made to the Exchange Plan: Should HHS use the State Plan Amendment process in place for Medicaid and CHIP	155.105(e)	183
26	To what extent should HHS place conflict of interest requirements on entities contracted for Medicaid Eligibility	155.110(b)	184
27	Governance board: to what extent should the categories of representatives with potential conflicts of interest be further specified and what types of representatives have potential conflicts of interest.	155.110(c)(3)	184
29	HHS may periodically review the accountability structure and governance principles of an Exchange: what should the recommended frequency of these reviews be?	155.110(f)	185
33	Seek comment on operational or policy concerns about the idea of subsidiary Exchanges that cover areas across State lines and on the extent to which we should allow more flexibility in the structure of a subsidiary Exchange.	155.140(c)	187
35	Which proposed threshold (2016 estimate) of national coverage should be used: CMS Office of the Actuary (93.6%) or CBO (95%) or an alternative	155.150(a)(2)	188
36	HHS proposes Exchanges announce the assessment of any user fees on health insurance issuers in advance of the plan year: should the final regulation other limit how and when user fees may be charged, and whether such fees should be assessed on an annual basis.	155.160(b)(4)	188
40	Seek comment on ways to streamline and prevent duplications of efforts by the Exchange call center and QHP issuers' customer call centers, but ensure that consumers have a variety of ways to learn about their coverage options and receive assistance on other health insurance coverage issues.	155.205	189-91
41	Exchange website: the Secretary must establish a standardized format for present coverage option information, and make a model Exchange website template available to states: to what extent might the Exchange website satisfy the need to provide plan comparison functionality using HealthCare.gov	155.205(b)	189-91
43-44	Seek comment about: HHS is considering a website req't that allows applicants and enrollees to store and access personal account information… and to minimize admin burden, encourage Exchanges to develop a feature for eligibility and enrollment experts, caseworkers,	155.205(b)	189

	Navigators, agents and brokers, and other application assisters to maintain records of individuals they have assisted w/application process.		
44	To what extent would states benefit from a model calculator (on website) and suggestions on its design	155.205(c)	191
46	Should HHS propose additional requirements on Exchanges to make determinations regarding conflicts of interest for Navigators	155.210(b)(1)(iv)	192
46	Should at least one of the two types of entities serving as Navigators include a community and consumer-focused non-profit organization; should Navigator grantees reflect a cross section of stakeholders?	155.210(b)(2)	192
46-7	Navigators cannot receive any compensation from Insurers for enrollment in Exchange, but CAN for enrolling outside (non-QHP plans). Seek comment on this, and whether there are ways to manage any potential conflict of interest that might arise	155.210(c)(2)	192
47	Seek comments on potential standards to ensure that information made available by Navigators is fair, accurate, and impartial	155.210(d)(2)	193
48	Cultural and Linguistic appropriateness for Navigator function; see comment regarding any specific standards HHS might issue through future rulemaking or additional guidance on these proposed requirements	155.210(d)(5)	193
48	Should Navigator program be operational no later than first day of initial open enrollment period? (Oct 2013)	155.210	191-93
50	What functions could web-based and other entities with experience in health plan enrollment contracted with Exchange perform, what is the potential scope of how these entities would interact with Exchanges and what standards should apply to an entity performing functions in place of or on behalf of an Exchange.	155.220	193-4
50	What are the practical implications, costs, and benefits to an Exchange that coordinates with web-based + other entities (to assist outreach and enrollment) and what are the related security issues	155.220	193-4
51	Should HHS codify examples and requirements that notices be provided in plain, language, and that notices are available in formats appropriate for people with disabilities (written, oral, etc) and those with limited English	155.230(b)	194
53	Seek comment on how to distinguish between individuals eligible for assistance under ACA and those who are not in light of the different definitions of “Indian” that apply for other Exchange provisions	155.240(b)	195
53	Seek comment regarding Exchange flexibility in establishing the premium payment process and what standards would be appropriate for the Fed gov’t to establish in regulations to ensure fiduciary accountability in the case of an Exchange that collects premiums	155.240	194-5
54	Should HHS, and if so, how, restrict the method of disposal of personally identifiable information collected by Exchanges?	155.260(a) + (b)	195-6
57	Are FIPPS (Fair Information Practice Principles) appropriate guidelines for privacy policies and if so, what is the best means to implement them?	155.260(b)(2), (3), + (4)	196
57	What is the aptness of adopting the HIPAA privacy model for	155.260(b)(2),	196

	exchanges?	(3), + (4)	
61	Should HHS codify a requirement for a specific frequency for enrollment transactions, such as in real time or daily, in the final rule?	155.400(b)	198
62	Should HHS codify a requirement that applicants may not be required to answer questions that are not pertinent to the eligibility and enrollment process?	155.405(a)	198
63	Should it be a requirement that individuals have the option to file an application in person?	155.405(c)(2)(iv)	199
64	Seek comment on the duration of the initial open enrollment period.	155.410(b)	199
66	Should HHS allow at least twice-monthly effective dates of coverage or complete flexibility to allow for coverage to begin any day for individuals who forgo receipt of advance tax credit for their first partial month or are not eligible?	155.410(c)	199-200
66	Should HHS codify requirements re: information in notice about open enrollment pertaining to 1) date annual open enrollment begins and ends 2) where individuals can get information 3) other relevant information	155.410(d)	200
66	Seek comment about proposed alternative open enrollment period of Nov 1-Dec 15	155.410(e)	200
66-7	Should Exchanges be required to automatically enroll individuals who received advance payments of the premium tax credit and are then dis-enrolled from a QHP because the QHP is no longer offered if such individual does not make a new QHP selection?	155.410	199-200
67	Should HHS codify requirements regarding automatic enrollment into new QHPs when there are mergers between issuers or when one QHP offered through a specific issuer is no longer offered but there are several other options with the same issuer?	155.410	199-200
67	How far should such automatic enrollment extend?	155.410	199-200
68	Seek comment on the alternatives raised for the special enrollment periods and whether others should have an alternate start date (see 155.420, p. 200-202)	155.420	200-202
69-70	Solicit comment on following provision: "If otherwise qualified individuals who maintained less than minimum essential coverage were granted a special enrollment period based on termination of such coverage, such individuals might wait until experiencing a significant health care need to enroll in a QHP through the Exchange by using a special enrollment period. This could create a problem of adverse selection"	155.420(d)(1)	201
70	Might states consider expanding the special enrollment period to include gaining dependents through life events in addition to marriage, birth, adoption, or placement for adoption.	155.420(d)(2)	201
71	Should the start of the 60 day special enrollment period be based on the date on which and individual experiences a change in eligibility or the date of the eligibility determination?	155.420(c)	201
72	Seek comment on the timing of the 60 day special enrollment in the case of someone who is eligible for advance premium tax credit	155.420(d)(6)	202

	payment but who's ESI (employer sponsored insurance) no longer qualifies, allowing them to waive the requirement to be uninsured prior to determination of eligibility.		
73	Seek comment on special enrollment period for those eligible for QHP due to a permanent move	155.420(d)(7)	202
73	Seek comment on the potential implications on the process for verifying Indian status.	155.420(d)(8)	202
74	HHS proposed an exception to the limitation that enrollees maintain a single level of coverage (bronze, silver, etc) through the year to avoid adverse section for new eligibility for advance payments of the premium tax credit or change in eligibility for cost sharing reductions.	155.420(f)	202
76	The last day of coverage is the day before the effective date of new coverage for an enrollee terminated due to obtaining new minimum essential coverage. How can Exchanges work with QHP issuer to implement this proposal, which is intended to ensure no double enrollment	155.430(d)(2)	204
81	HHS seeks comment on whether employers should be able to limit employee choice to a specific level of coverage (eg, bronze, silver, etc) or just one QHP in a SHOP	155.705(b)(3)	206
81	To avoid potential for risk selection among plans (adverse selection) HHS invites comments on proposed flexibility for SHOPs to use a risk adjustment program or requiring employee choice within a level of cost-sharing.	155.705(b)(3)	206
81-2	Should QHPs offered in the SHOP be required to waive application of minimum participation rules at the level of the QHP or issuer; should a minimum participation rule be applied at the SHOP level? If so, how should the rate be calculated, what should the rate be, and should it be established by federal regulation?	155.705(b)(3)	206
83	Should SHOPs require all QHPs to make any changes to rates quarterly, monthly, annually, or some other (uniform) time period?	155.705(b)(6)	206
84	What rates should be used to determine premiums during the plan year for employees hired after eligibility date?	155.705(b)(6)	206
85-6	What methods are appropriate to use to determine employer group size?	155.710(b)(1)	207
89	A SHOP must notify each qualified employee in the event of their employer's withdrawl and their termination of coverage prior to such withdrawl and termination. Should employees also receive notification about eligibility for special enrollment periods on the Exchange and about the process of being determined eligible for advance payments of the premium tax credit and cost-sharing reductions, Medicaid, and CHIP?	155.715(g)	210
91	A SHOP must maintain records of qualified employer participation and qualified employee enrollment in the SHOP, which must be reported to HHS: should HHS establish target dates or guidelines so that multi-state qualified employers are subject to consistent rules?	155.715(f)	210
92	HHS proposes a rolling enrollment process in a SHOP, with plan year based on enrollment date, not on calendar year: HHS invites comment	155.725(b)	213

	on this.		
93	Should employers receive 30 days advance notice that the annual election period is approaching?	155.725(d)	213
93	Annual employee enrollment should occur at a fixed point during the plan year (not calendar year)	155.725(e)	213
94	HHS invites comments about their approach in differentiating the individual and small group market , and the proposed structure for initial, rolling, and annual open enrollment through the SHOP	155.725	212-14
95	What information should employers be required to collect from employees for SHOP enrollment application?	155.730(b)	214
104	HHS seeks comment on how best to align the rate review requirements between the state and fed regulations, and Exchange to work with State Insurance Department	155.1020	217
105	Exchanges are required to collect transparency information from QHPs/ QHPs must submit said transparency information to the Exchange, HHS, and other entities. The same requirements will apply to all group health plans and health insurance issuers in the individual and group markets under section 2715 of the PHS Act. HHS seeks comment on this process so that the Department of Labor can update and harmonize its rules for group health plans disclosures.	155.1040(a)	217
108	What minimum qualitative or quantitative standards (in addition to “sufficient choice of providers”) should Exchanges use to determine network adequacy standards of QHPs?	155.1050	218
108	Should Exchanges establish requirement that QHPs maintain 1)sufficient numbers and types of providers; 2)reasonable proximity of participating providers to enrollees; 3) ongoing monitoring process to ensure sufficiency of network; 4) process to ensure an enrollee can obtain necessary out of network care at no additional cost if no network provider is reasonably accessible	155.1050	218
109	Should the standard require Exchanges to ensure that QHPs’ provider networks provide sufficient access to care for all enrollees?	155.1050	218
111	Should some of the requirements on QHP issuers also apply to stand-alone dental plans as a Federal minimum and what limits Exchanges may face on placing requirements on dental plans given that they are excepted benefits.	155.1065	219
111	Should HHS set specific operational minimum standards? (Substantial operational issues exist with allocating advance payments of the premium tax credit and calculating actuarial value when stand-alone dental plans segment coverage of essential health benefits)	155.1065	219
112	Should all dental benefits be offered and priced as stand-alone plans to facilitate comparison of dental offerings even though this may create an administrative burden on Exchanges and QHP issuers?	155.1065	219
112	Exchanges may determine the frequency for recertifying QHPs, should HHS require a more specific time frame?	155.1075(a)	219
112	Exchanges must complete recertification processes by or before Sept 15 of the applicable calendar year. Is this deadline appropriate?	155.1075(b)	219
114	HHS requests comments on the decertification (of QHPs) process and	155.1080	219-

	what authorities could be extended to the Exchange to make the process more efficient.		20
122	Should insurance issuers submit required transparency information (such as claims payment policies, disenrollment data, and more) or just make the information available to the Exchanges and other entities	156.220(a) + (b)	226-7
124	What is the best means for an Exchange to monitor QHP issuers' marketing practices to determine whether they have discouraged enrollment of individuals with significant health needs?	156.225(b)	227
124	HHS seeks comment on applying a broad prohibition against unfair or deceptive marketing practices by all QHP issuers, their officials, agents, and representatives.	156.225	227
125	HHS seeks comment on a standard that QHP issuers do not misrepresent the benefits, advantages, conditions, exclusions, limitations, or terms of a QHP, especially in relation to vulnerable or already enrolled (in public program) populations.	156.225	227
126	Seek comment on standards to ensure QHP issuers maintain up-to-date provider directories.	156.230(b)	228
128	How should "sufficient number of essential community providers" be defined (regarding ensuring that QHP issuers have the providers necessary for timely access for low-income, medically underserved individuals)?	156.235(a)	228
128	Should "staff model" plans be exempted from the essential community provider requirements?	156.235	228
129	What types of providers should be included in the definition of an essential community provider?	156.235(b)	228
131	Seek comment on options for FQHC (federally qualified health centers) payment conflicts	156.235	228
131	Seek comment on establishing requirements regarding reimbursement of Indian health providers.	156.235	228
131	How might the payment requirement under IHCIA (Indian Health Care Improvement Act) be reconciled with the essential community provider payment requirement in the ACA	156.235	228
131	HHS invites comment on other special accommodations that must be made when contracting with Indian health providers	156.235	228
132	Should HHS develop a standard contract addendum containing all issues that would apply to QHP issuers when contracting with Indian health providers?	156.235	228
132	What standards should HHS establish under the "direct primary care medical home"	156.245	228
135	How should family rating categories be structured while adhering to the age and tobacco rating rule (can only be applied to relevant individuals—not the whole family).	156.255(c)	229
135	How should four family categories be applied when performing risk adjustment?	156.255(c)	229
135	Seek comment on alternatives to four categories for defining family composition.	156.255(c)	229
136	How shall the number of categories offered by QHP issuers be balanced	156.255(c)	229

	in order to reduce potential consumer confusion?		
136	Should QHP issuers be required to cover an enrollee's tax household, in order to facilitate the administration of the premium tax credit?	156.255(c)	229
138	How often should QHP issuers receive enrollment information electronically from the Exchange?	156.265(c)	230
138	Seek comment on the contents of the enrollment packet QHP issuers are required to provide to enrollees in Exchange: possible contents include enrollment card, information how to access care, summary of benefit and coverage document, and information on how to access the provider directory and drug formulary and submit a request for a hard copy.	156.265(e)	231
141	What should the required elements for notice to enrollees who are delinquent on premium payments be (for example, amount of delinquent payment, possible date of termination, payment options, timing and frequency of such a notice, etc.)	156.270(c)	231-2
142	By what standards should HHS recognize the entities that accredit QHPs?	156.275	232-3
143	HHS would like comment on the model guidelines concerning segregation of funds for abortion services: "Pre-Regulatory Model Guidelines Under Section 1303 of the Affordable Care Act" (www.whitehouse.gov/sites/default/files/omb/assets/financial_pdf/segregation_2010-09-20.pdf)	156.280(e)	234-6
144	Should QHPs in the SHOP be required to allow employers to offer dependent coverage?	156.285	238-9
146	What should be included in the content of the non-renewal notice QHPs that elect not to seek re-certification with the Exchange must provide in written form to each enrollee?	156.290(b)	240
147	How long should enrollees be able to continue to receive coverage from a decertified plan (how long can they have to enroll in other coverage)?	156.290(c)	240
148	How shall a QHP issuer whose contracted Pharmacy Benefit Manager operates its own mail order pharmacy meaningfully report on the aggregate difference between what the QH issuer pays the PBM and the PBM pays the mail order pharmacy?	156.295(a)(3)	241
148	HHS seeks comment on potential definitions for "rebates," "discounts," and "price concessions." (Considering the use of "direct and indirect remuneration" used in regulations related to the Medicare Prescription Drug Benefit Program.)	156.295	240-2
148	Should PBMs (Pharmacy Benefit Managers) be defined to include any entity that performs activities such as prescription drug claims processing, negotiation with prescription drug manufacturers, the development and maintenance of pharmacy networks, or the distribution of prescription drugs on the behalf of the QHP issuer on behalf of a QHP issuer?	156.295	240-2
149	HHS seeks comments on the collection of Information Requirements *(for the sections listed in the next column)* (Paperwork Reduction Act of 1995):	155.105 155.110 155.205	182 184 189

	The need for the information collection and its usefulness in carrying out the proper functions of the agency. The accuracy of the estimate of the information collection burden. The quality, utility, and clarity of the information to be collected. Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.	155.400-430 155.715-725 155.1040-1080 156.210-290	197+ 208+ 217+ 226+